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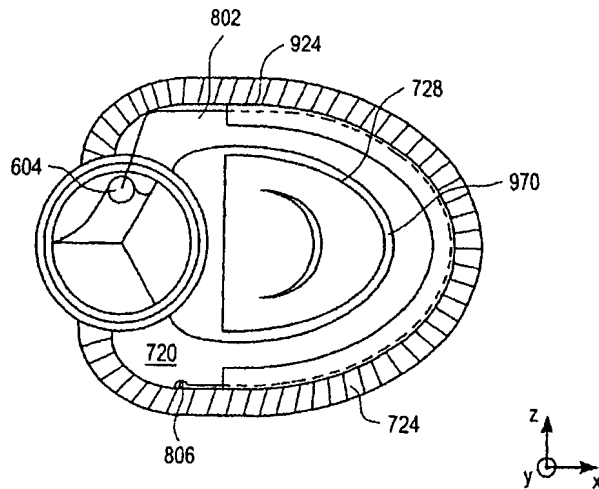
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(54) Title: METHOD AND APPARATUS FOR PERFORMING CATHETER-BASED ANNULOPLASTY



(57) Abstract: The present invention relates to a minimally invasive method of performing annuloplasty. According to one aspect of the present invention, a method for performing a procedure on a mitral valve (728) of a heart includes inserting an implant (924) into a left ventricle and orienting the implant in the left ventricle substantially below the mitral valve. The implant (924) and tissue (970) around the mitral valve (728) are connected and tension is provided to the implant, in one embodiment, in order to substantially reduce an arc length associated with the mitral valve (728). In another embodiment, the implant (924) is inserted into the left ventricle through the aorta and the aortic valve.

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## METHOD AND APPARATUS FOR CATHETER-BASED ANNULOPLASTY

### BACKGROUND OF THE INVENTION

#### 1. Field of Invention

5           The present invention relates generally to techniques for treating mitral valve insufficiencies such as mitral valve leakage. More particularly, the present invention relates to systems and methods for treating a leaking mitral valve in a minimally invasive manner.

#### 10    2. Description of the Related Art

          Congestive heart failure (CHF), which is often associated with an enlargement of the heart, is a leading cause of death. As a result, the market for the treatment of CHF is becoming increasingly prevalent. For instance, the treatment of CHF is a leading expenditure of Medicare and Medicaid dollars in the United States of  
15   America. Typically, the treatment of CHF enables many who suffer from CHF to enjoy an improved quality of life.

          Referring initially to Fig. 1, the anatomy of a heart, specifically the left side of a heart, will be described. The left side of a heart 104 includes a left atrium 108 and a  
20   left ventricle 112. An aorta 114 receives blood from left ventricle 112 through an aortic valve 120, which serves to prevent regurgitation of blood back into left ventricle 112. A mitral valve 116 is disposed between left atrium 108 and left ventricle 112, and effectively controls the flow of blood between left atrium 108 and left ventricle 112.

25           Mitral valve 116, which will be described below in more detail with respect to Fig. 2a, includes an anterior leaflet and a posterior leaflet that are coupled to cordae tendonae 124 which serve as "tension members" that prevent the leaflets of mitral valve 116 from opening indiscriminately. When left ventricle 112 contracts, cordae  
30   tendonae 124 allow the anterior leaflet to open upwards until limited in motion by cordae tendonae 124. Normally, the upward limit of opening corresponds to a

meeting of the anterior and posterior leaflets and the prevention of backflow. Cordae tendonae 124 arise from a columnae carnae 128 or, more specifically, a muscoli papillares of columnae carnae 128.

5           Left ventricle 112 includes trabeculae 132 which are fibrous cords of connective tissue that are attached to wall 134 of left ventricle 112. Trabeculae 132 are also attached to an interventricular septum 136 which separates left ventricle 112 from a right ventricle (not shown) of heart 104. Trabeculae 132 are generally located in left ventricle 112 below columnae carnae 128.

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Fig. 2a is a cut-away top-view representation of mitral valve 116 and aortic valve 120. Aortic valve 120 has a valve wall 204 that is surrounded by a skeleton 208a of fibrous material. Skeleton 208a may generally be considered to be a fibrous structure that effectively forms a ring around aortic valve 120. A fibrous ring 208b, 15 which is substantially the same type of structure as skeleton 208a, extends around mitral valve 116. Mitral valve 116 includes an anterior leaflet 212 and a posterior leaflet 216, as discussed above. Anterior leaflet 212 and posterior leaflet 216 are generally thin, flexible membranes. When mitral valve 116 is closed (as shown in Fig. 2a), anterior leaflet 212 and posterior leaflet 216 are generally aligned and 20 contact one another to create a seal. Alternatively, when mitral valve 116 is opened, blood may flow through an opening created between anterior leaflet 212 and posterior leaflet 216.

Many problems relating to mitral valve 116 may occur and these 25 insufficiencies may cause many types of ailments. Such problems include, but are not limited to, mitral regurgitation. Mitral regurgitation, or leakage, is the backflow of blood from left ventricle 112 into the left atrium 108 due to an imperfect closure of mitral valve 116. That is, leakage often occurs when a gap is created between anterior leaflet 212 and posterior leaflet 216.

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In general, a relatively significant gap may exist between anterior leaflet 212 and posterior leaflet 216 (as shown in Fig. 2b) for a variety of different reasons. For



example, a gap may exist due to congenital malformations, because of ischemic disease, or because a heart has been damaged by a previous heart attack. A gap may also be created when congestive heart failure, *e.g.*, cardiomyopathy, or some other type of distress causes a heart to be enlarged. When a heart is enlarged, the walls of the heart, *e.g.*, wall 134 of a left ventricle, may stretch or dilate, causing posterior leaflet 216 to stretch. It should be appreciated that anterior leaflet 212 generally does not stretch. As shown in Fig. 2b, a gap 220 between anterior leaflet 212 and stretched posterior leaflet 216 is created when wall 134 stretches. Hence, due to the existence of gap 220, mitral valve 116 is unable to close properly, and may begin to leak.

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Leakage through mitral valve 116 generally causes a heart to operate less efficiently, as the heart must work harder to maintain a proper amount of blood flow therethrough. Leakage through mitral valve 116, or general mitral insufficiency, is often considered to be a precursor to CHF. There are generally different levels of symptoms associated with heart failure. Such levels are classified by the New York Heart Association (NYHA) functional classification system. The levels range from a Class 1 level which is associated with an asymptomatic patient who has substantially no physical limitations to a Class 4 level which is associated with a patient who is unable to carry out any physical activity without discomfort, and has symptoms of cardiac insufficiency even at rest. In general, correcting for mitral valve leakage may be successful in allowing the NYHA classification grade of a patient to be reduced. For instance, a patient with a Class 4 classification may have his classification reduced to Class 3 and, hence, be relatively comfortable at rest.

Treatments used to correct for mitral valve leakage or, more generally, CHF, are typically highly invasive, open-heart surgical procedures. Ventricular assist devices such as artificial hearts may be implanted in a patient whose own heart is failing. The implantation of a ventricular assist device is often expensive, and a patient with a ventricular assist device must be placed on extended anti-coagulant therapy. As will be appreciated by those skilled in the art, anti-coagulant therapy reduces the risk of blood clots being formed, as for example, within the ventricular assist device. While reducing the risks of blood clots associated with the ventricular

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assist device is desirable, anti-coagulant therapies may increase the risk of uncontrollable bleeding in a patient, *e.g.*, as a result of a fall, which is not desirable.

5 Rather than implanting a ventricular assist device, bi-ventricular pacing devices similar to pace makers may be implanted in some cases, *e.g.*, cases in which a heart beats inefficiently in a particular asynchronous manner. While the implantation of a bi-ventricular pacing device may be effective, not all heart patients are suitable for receiving a bi-ventricular pacing device. Further, the implantation of a bi-ventricular pacing device is expensive.

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Open-heart surgical procedures which are intended to correct for mitral valve leakage, specifically, involve the implantation of replacement valves. Valves from animals, *e.g.*, pigs, may be used to replace a mitral valve 116 in a human. While the use of a pig valve may relatively successfully replace a mitral valve, such valves  
15 generally wear out, thereby requiring additional open surgery at a later date. Mechanical valves, which are less likely to wear out, may also be used to replace a leaking mitral valve. However, when a mechanical valve is implanted, there is an increased risk of thromboembolism, and a patient is generally required to undergo extended anti-coagulant therapies.

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A less invasive surgical procedure involves heart bypass surgery associated with a port access procedure. For a port access procedure, the heart may be accessed by cutting a few ribs, as opposed to opening the entire chest of a patient. In other words, a few ribs may be cut in a port access procedure, rather than opening a  
25 patient's sternum.

One open-heart surgical procedure that is particularly successful in correcting for mitral valve leakage and, in addition, mitral regurgitation, is an annuloplasty procedure. During an annuloplasty procedure, an annuloplasty ring may be implanted  
30 on the mitral valve to cause the size of a stretched mitral valve 116 to be reduced to a relatively normal size. Fig. 3 is a schematic representation of an annuloplasty ring. An annuloplasty ring 304 is shaped approximately like the contour of a normal mitral

valve. That is, annuloplasty ring 304 is shaped substantially like the letter "D." Typically, annuloplasty ring 304 may be formed from a rod or tube of biocompatible material, *e.g.*, plastic, that has a DACRON mesh covering.

5           In order for annuloplasty ring 304 to be implanted, a surgeon surgically attaches annuloplasty ring 304 to the mitral valve on the atrial side of the mitral valve. Conventional methods for installing ring 304 require open-heart surgery which involve opening a patient's sternum and placing the patient on a heart bypass machine. As shown in Fig. 4, annuloplasty ring 304 is sewn to a posterior leaflet 318  
10           and an anterior leaflet 320 of a top portion of mitral valve 316. In sewing annuloplasty ring 304 onto mitral valve 316, a surgeon generally alternately acquires a relatively large amount of tissue from mitral tissue, *e.g.*, a one-eighth inch bite of tissue, using a needle and thread, followed by a smaller bite from annuloplasty ring 304. Once a thread has loosely coupled annuloplasty ring 304 to mitral valve tissue,  
15           annuloplasty ring 304 is slid onto mitral valve 316 such that tissue that was previously stretched out, *e.g.*, due to an enlarged heart, is effectively pulled in using tension applied by annuloplasty ring 304 and the thread which binds annuloplasty ring 304 to the mitral valve tissue. As a result, a gap, such as gap 220 of Fig. 2b, between anterior leaflet 320 and posterior leaflet 318 may be substantially closed off. After  
20           the mitral valve is shaped by ring 304, the anterior and posterior leaflets 320, 318 will reform to create a new contact line and will enable mitral valve 318 to appear and to function as a normal mitral valve.

          Once implanted, tissue generally grows over annuloplasty ring 304, and a line  
25           of contact between annuloplasty ring 304 and mitral valve 316 will essentially enable mitral valve 316 to appear and function as a normal mitral valve. Although a patient who receives annuloplasty ring 304 may be subjected to anti-coagulant therapies, the therapies are not extensive, as a patient is only subjected to the therapies for a matter of weeks, *e.g.*, until tissue grows over annuloplasty ring 304.

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          A second surgical procedure which is generally effective in reducing mitral valve leakage involves placing an edge-to-edge suture in the mitral valve. With

reference to Fig. 5, such a surgical procedure, *e.g.*, an Alfieri stitch procedure or a bow-tie repair procedure, will be described. An edge-to-edge stitch 404 is used to stitch together an area at approximately the center of a gap 408 defined between an anterior leaflet 420 and a posterior leaflet 418 of a mitral valve 416. Once stitch 404 is in place, stitch 404 is pulled in to form a suture which holds anterior leaflet 420 against posterior leaflet 418, as shown. By reducing the size of gap 408, the amount of leakage through mitral valve 416 may be substantially reduced.

Although the placement of edge-to-edge stitch 404 is generally successful in reducing the amount of mitral valve leakage through gap 408, edge-to-edge stitch 404 is conventionally made through open-heart surgery. In addition, the use of edge-to-edge stitch 404 is generally not suitable for a patient with an enlarged, dilated heart, as blood pressure causes the heart to dilate outward, and may put a relatively large amount of stress on edge-to-edge stitch 404. For instance, blood pressure of approximately 120/80 or higher is typically sufficient to cause the heart to dilate outward to the extent that edge-to-edge stitch 404 may become undone, or tear mitral valve tissue.

While invasive surgical procedures have proven to be effective in the treatment of mitral valve leakage, invasive surgical procedures often have significant drawbacks. Any time a patient undergoes open-heart surgery, there is a risk of infection. Opening the sternum and using a cardiopulmonary bypass machine has also been shown to result in a significant incidence of both short and long term neurological deficits. Further, given the complexity of open-heart surgery, and the significant associated recovery time, people who are not greatly inconvenienced by CHF symptoms, *e.g.*, people at a Class 1 classification, may choose not to have corrective surgery. In addition, people who most need open heart surgery, *e.g.*, people at a Class 4 classification, may either be too frail or too weak to undergo the surgery. Hence, many people who may benefit from a surgically repaired mitral valve may not undergo surgery.

Therefore, what is needed is a minimally invasive treatment for mitral valve leakage. Specifically, what is desired is a method for reducing leakage between an anterior leaflet and a posterior leaflet of a mitral valve that does not require conventional surgical intervention.

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#### SUMMARY OF THE INVENTION

The present invention relates to a non-invasive method of performing annuloplasty. According to one aspect of the present invention, a method for performing a procedure on a mitral valve of a heart includes inserting an implant into a left ventricle and orienting the implant in the left ventricle substantially below the mitral valve. The implant may be attached to tissue near the mitral valve. In one embodiment, the implant is shortened in order to substantially reduce an arc length associated with the mitral valve. In another embodiment, the implant is inserted to the left ventricle through the aorta and the aortic valve.

In still another embodiment, connecting the implant and the tissue includes introducing a catheter into the left ventricle using a guide element as a track. The catheter includes at least one pointed wire which carries a coupling element and has a tip section that may be substantially pushed through the implant and the tissue to substantially couple the implant with the tissue. In such an embodiment, the coupling element may be a T-bar.

Performing an annuloplasty on a mitral valve by accessing the left ventricle of the heart using a catheter enables complicated surgical procedures to be avoided when treating mitral valve leakage. Avoiding surgical procedures generally makes annuloplasty more accessible to patients who may benefit from annuloplasty. As mitral valve leakage is often considered to be an early indicator of congestive heart failure, a non-invasive annuloplasty procedure which corrects for leakage problems may greatly improve the quality of life of many patients who might not be suitable for invasive annuloplasty procedures.

According to another aspect of the present invention, a method for accessing the left ventricle of a heart includes introducing an elongated body into the aorta, and passing at least a portion of the elongated body through the aortic valve. Once the  
5 portion is passed through the aortic valve, the portion is located, or positioned, in the left ventricle. In one embodiment, locating the portion in the left ventricle involves positioning the portion in the space between a plane associated with the mitral valve and a plane associated with the papillary muscles of the left ventricle. In such an embodiment, the elongated body may be an implant, and locating the portion in the  
10 left ventricle may further involve positioning the implant substantially against tissue near the mitral valve.

In accordance with still another aspect of the present invention, a method for performing annuloplasty includes accessing the left ventricle to provide an implant  
15 such as a tensionable arrangement to the left ventricle. Once the left ventricle is accessed, the tensionable arrangement is coupled to fibrous tissue around a mitral valve of the heart. The tensionable arrangement is coupled to a ventricular side of the mitral valve. Finally, the tensionable arrangement is tensioned such that it substantially reduces an arc length associated with the mitral valve. In one  
20 embodiment, the tensionable arrangement is an implant, and tensioning the tensionable arrangement involves substantially collapsing the implant.

According to yet another aspect of the present invention, a device which is suitable for use in an annuloplasty procedure includes a structure, a mesh, and a  
25 tensioning element. The structure is a spring-like element that is configured to be compressed onto itself when tension is applied. The mesh is a woven mesh that is arranged over the structure, and the tensioning element is arranged to apply tension to the structure. The device is such that when the device is coupled to fibrous tissue in proximity to the mitral valve of a heart, the tensioning element causes the device to  
30 reduce an arc length associated with the mitral valve. In one embodiment, device is suitable for being coupled to a ventricular side of the mitral valve. In another embodiment, the device includes a coupler which extends through the structure and

the mesh to couple the device to the fibrous tissue. In such an embodiment, the coupler may take the form of a T-bar.

5 In accordance with still another aspect of the present invention, a device for use in an annuloplasty procedure includes a compressible member and a shortening device. The compressible member is movable between an open uncompressed position for insertion into a left ventricle through a catheter and a closed position. The shortening device is operable to move the compressible member between the open uncompressed position and the closed position. In general, the device is  
10 positioned to reduce an opening of a mitral valve. In one embodiment, the device also includes mesh covering that extends over at least a portion of the compressible member.

These and other advantages of the present invention will become apparent  
15 upon reading the following detailed descriptions and studying the various figures of the drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

20 The invention may best be understood by reference to the following description taken in conjunction with the accompanying drawings in which:

Fig. 1 is a cross-sectional front-view representation of the left side of a human heart.

25 Fig. 2a is a cut-away top-view representation of the mitral valve and the aortic valve of Fig. 1.

Fig. 2b is a cut-away representation of a stretched mitral valve and an aortic valve.

Fig. 3 is a representation of an annular ring that is suitable for use in performing a conventional annuloplasty procedure.

30 Fig. 4 is a representation of a mitral valve and an aortic valve after the annular ring of Fig. 3 has been implanted.

Fig. 5 is a representation of a mitral valve and an aortic valve after a single edge-to-edge suture has been applied to reduce mitral regurgitation.

Fig. 6a is a representation of a delivery tube and a J-catheter in accordance with an embodiment of the present invention.

5        Fig. 6b is a cut-away front view of the left side of a heart in which the delivery tube and the J-catheter of Fig. 6a have been inserted in accordance with an embodiment of the present invention.

Fig. 7a is a representation of a catheter assembly in accordance with an embodiment of the present invention.

10       Fig. 7b is a cross-sectional representation of the catheter assembly of Fig. 7a in accordance with an embodiment of the present invention.

Fig. 7c is a cut-away top-view representation of a left ventricle in which the gutter catheter of Figs. 7a and 7b has been positioned in accordance with an embodiment of the present invention.

15       Fig. 8 is a cut-away top-view representation of a left ventricle in which a guide wire has been positioned in accordance with an embodiment of the present invention.

Fig. 9a is a representation of a portion of an implant in accordance with an embodiment of the present invention.

20       Fig. 9b is a cut-away top-view representation of a left ventricle in which an implant has been positioned in accordance with an embodiment of the present invention.

Fig. 9c is a cross-sectional front-view representation of a left ventricle in which the implant of Fig. 9b and a balloon have been inserted in accordance with an embodiment of the present invention.

25       Fig. 10 is a representation of a T-bar delivery catheter in accordance with an embodiment of the present invention.

Fig. 11a illustrates an implant that is coupled to fibrous tissue around a mitral valve before tension has been applied to the implant in accordance with an embodiment of the present invention.

30       Fig. 11b illustrates the implant of Fig 11a after tension has been applied to the implant in accordance with an embodiment of the present invention.



Fig. 12 is a process flow diagram which illustrates the steps associated with one method of performing annuloplasty using a catheter in accordance with an embodiment of the present invention.

5 Fig. 13a is a cut-away representation of a left ventricle in which a catheter has been inserted in accordance with a second embodiment of the present invention.

Fig. 13b is a cross-sectional representation of a left ventricle in which the catheter of Fig. 13a has been inserted in accordance with the second embodiment of the present invention.

10 Fig. 13c is a representation of a clip which is coupled to an anterior leaflet and a posterior leaflet in accordance with the second embodiment of the present invention.

#### DETAILED DESCRIPTION OF THE EMBODIMENTS

15 Invasive, open-heart surgical procedures are generally effective in the treatment of mitral valve leakage. However, open-heart surgical procedures may be particularly hazardous to some patients, *e.g.*, frail patients or patients who are considered as being very ill, and undesirable to other patients, *e.g.*, patients who are asymptomatic and do not wish to undergo a surgical procedure. As such, open-heart  
20 surgical procedures to correct mitral valve leakage or, more generally, mitral valve insufficiency, are not suitable for many patients who would likely benefit from reducing or eliminating the mitral valve leakage.

A catheter-based annuloplasty procedure enables annuloplasty to be performed  
25 on a patient without requiring that the patient undergo open-heart surgery, or be placed on cardiopulmonary bypass. Catheters may be introduced into the left ventricle of a heart through the aorta to position a guide wire and an implant on the ventricular side of a mitral valve, *i.e.*, under a mitral valve. Catheters may also be used to couple the implant to fibrous tissue associated with the skeleton of the heart  
30 around the mitral valve, and to reduce leakage between an anterior leaflet of the mitral valve and a posterior leaflet of the mitral valve by applying tension to the implant.

The use of catheters to perform an annuloplasty procedure enables the annuloplasty procedure to be performed without open-heart surgery, and without a bypass procedure. Recovery time associated with the annuloplasty, as well as the risks associated with annuloplasty, may be substantially minimized. As a result,  
5 annuloplasty becomes a more accessible procedure, since many patients who might previously not have received treatment for mitral valve leakage, *e.g.*, frail patients and asymptomatic patients, may choose to undergo catheter-based annuloplasty.

To begin a catheter-based annuloplasty procedure, a delivery tube and a J-  
10 catheter may be inserted into a left ventricle of the heart through the aorta. Inserting the delivery tube and the J-catheter through the aorta enables the left ventricle of the heart to be reached substantially without coming into contact with trabeculae or the cordae tendonae in the left ventricle. Fig. 6a is a diagrammatic representation of a delivery tube and a J-catheter in accordance with an embodiment of the present  
15 invention. Delivery tube 604 has a substantially circular cross section, and is configured to receive a J-catheter 608. J-catheter 608 is arranged to move longitudinally through an opening in delivery tube 604 as needed.

In general, delivery tube 604 is an elongated body which may be formed from  
20 a flexible, durable, biocompatible material such as nylon, urethane, or a blend of nylon and urethane, *e.g.*, PEBAX®. Likewise, J-catheter 608, which is also an elongated body, may also be formed from a biocompatible material. A material used to form J-catheter 608 is typically also relatively flexible. In the described embodiment, a tip of J-catheter 608 is rigid enough to allow the tip of J-catheter 608  
25 to maintain a relatively curved shape, *e.g.*, a “J” shape. The curve in J-catheter 608 is configured to facilitate the positioning of a gutter catheter, as will be described below with respect to Figs. 7a-c.

Fig. 6b is a schematic representation of delivery tube 604 and J-catheter 608  
30 positioned within a heart in accordance with an embodiment of the present invention. As shown, after delivery tube 604 and J-catheter 608 are effectively “snaked” or inserted through a femoral artery, portions of delivery tube 604 and of J-catheter 608

are positioned within an aorta 620 of a heart 616. A tip 626 of J-catheter 608, which is substantially oriented at a right angle from the body of J-catheter 608, and an end of delivery tube 604 are oriented such that they pass through an aortic valve 630. Hence, an end of delivery tube 604 and tip 626 are positioned at a top portion of left ventricle 5 624, where wall 632 of left ventricle 624 is relatively smooth. The relative smoothness of the top portion of left ventricle 624 enables a catheter to be properly positioned within left ventricle 624 by guiding the tip of the catheter along wall 632. In one embodiment, tip 626 is oriented such that it is positioned approximately just below a mitral valve 628 on the ventricular side of mitral valve 628.

10

Once positioned within left ventricle 624, J-catheter 608 may be rotated within delivery tube 604 such that tip 626 is may enable a gutter catheter fed therethrough to run along the contour of wall 632. Typically, the gutter catheter runs along the contour of wall 632 in an area that is effectively defined between a plane associated 15 with papillary muscles 640, a plane associated with the posterior leaflet of mitral valve 628, cordae tendonae 642, and wall 632. A "gutter" is located in such an area or region and, more specifically, is positioned substantially right under mitral valve 628 where there is a relatively insignificant amount of trabeculae.

20

With reference to Figs. 7a-7c, a gutter catheter will be described in accordance with an embodiment of the present invention. A gutter catheter 704, which is part of a catheter assembly 702 as shown in Fig. 7a, is arranged to be extended through J-catheter 626 such that gutter catheter 704 may be steered within a left ventricle just beneath a mitral valve. Gutter catheter 704, which may include a balloon tip (not 25 shown), is typically formed from a flexible material such as nylon, urethane, or PEBAX®. In one embodiment, gutter catheter 704, which is steerable, may be formed using a shape memory material.

As shown in Figs. 7a and Fig. 7b, which represents a cross section of catheter 30 assembly 702 taken at a location 710, gutter catheter 704 is at least partially positioned within J-catheter 608 which, in turn, is at least partially positioned within delivery tube 604. Gutter catheter 704 may be free to rotate within and extend

through J-catheter 608, while J-catheter 608 may be free to rotate within and extend through delivery tube 604.

Referring next to Fig. 7c, the positioning of gutter catheter 704 within a left  
5 ventricle of the heart will be described in accordance with an embodiment of the  
present invention. It should be appreciated that the representation of gutter catheter  
704 within a left ventricle 720 has not been drawn to scale, for ease of illustration and  
ease of discussion. For instance, the distance between a wall 724 of left ventricle 720  
and a mitral valve 728 has been exaggerated. In addition, it should also be  
10 appreciated that the positioning of delivery tube 604 and, hence, J-catheter 608 and  
gutter catheter 704 within aortic valve 732 may vary.

Gutter catheter 704 protrudes through tip 626 of J-catheter 608, and, through  
steering, essentially forms an arc shape similar to that of mitral valve 728 along the  
15 contour of a wall 724 of left ventricle 720 just beneath mitral valve 728, *i.e.*, along the  
gutter of left ventricle 720. Wall 724 of left ventricle 720 is relatively smooth just  
beneath mitral valve 728, *i.e.*, generally does not include trabeculae. Hence, inserting  
catheter assembly 702 through an aortic valve 732 into an upper portion left ventricle  
720 allows gutter catheter 704 to be navigated within left ventricle 720 along wall 724  
20 substantially without being obstructed by trabeculae or cordae tendoneae.

Gutter catheter 704 generally includes an opening or lumen (not shown) that is  
sized to accommodate a guide wire through which a guide wire may be inserted. The  
opening may be located along the central axis of gutter catheter 704, *i.e.*, central axis  
25 730 as shown in Fig. 7a. Delivering a guide wire through gutter catheter 704 enables  
the guide wire to effectively follow the contour of wall 724. In general, the guide  
wire may include an anchoring tip which enables the guide wire to be substantially  
anchored against wall 724. Fig. 8 is a diagrammatic top-view cut-away representation  
of a left side of a heart in which a guide wire has been positioned in accordance with  
30 an embodiment of the present invention. It should be appreciated that the  
representation of the left side of a heart in Fig. 8 has not been drawn to scale, and that  
various features have been exaggerated for ease of discussion. A guide wire 802 is

positioned along wall 724 of left ventricle 720. Once guide wire 802 is inserted through gutter catheter 704 of Figs. 7a-7c, and anchored against wall 724 using an anchoring tip 806, gutter catheter 704, along with J-catheter 708, are withdrawn from the body of the patient. It should be appreciated that delivery tube 604 typically  
5 remains positioned within the aorta after guide wire 802 is anchored to wall 724.

Guide wire 802, which may be formed from a material such as stainless steel or a shape memory material, is generally anchored such that guide wire 802 effectively passes along a large portion of wall 724. Typically, guide wire 802 serves  
10 as a track over which an implant may be positioned. With reference to Fig. 9a, one embodiment of an implant will be described in accordance with the present invention. A section 904 of an implant includes an opening 908 therethrough which is arranged to fit over a guide wire, *i.e.*, guide wire 802 of Fig. 8. In general, an implant is sized to be inserted through a femoral artery, an aorta, and an aortic valve. Section 904  
15 includes a biocompatible structure 912 over which a biocompatible woven mesh 916 is placed. Mesh 916 enables mitral valve tissue regrowth to occur in and around mesh 916 once the implant is positioned under the mitral valve. While structure 912 may take a variety of different forms, in one embodiment, structure may be formed as an open spring element which may effectively be shortened or collapsed onto itself, *e.g.*,  
20 when tension is applied to an overall implant as will be described below with respect to Figs. 11a and 11b.

Fig. 9b is a cut-away top-view representation of a left side of a heart in which an implant has been inserted over a guide wire in accordance with an embodiment of  
25 the present invention. It should be understood that the relative dimensions of features of the portion of the heart shown in Fig. 9b are not to scale, and some dimensions have been exaggerated for purposes of discussion. An implant 924 is positioned over guide wire 802 such that implant 924 substantially follows the curved contour of mitral valve 728 and, hence, fibrous tissue 970 around mitral valve 728. That is,  
30 implant 924 is shaped approximately like a horseshoe. Guide wire 802 effectively supports implant 924 to position implant 924 substantially below mitral valve 728 in left ventricle 720.

As discussed above with respect to Fig. 5, implant 924 may be coupled to a balloon or balloons which may be inflated to effectively push implant 924 up against a bottom side of mitral valve 728. With reference to Fig. 9c, the positioning of  
5 implant 924 against the bottom side of mitral valve 728 will be described in accordance with an embodiment of the present invention. Fig. 9c is a diagrammatic cross-sectional side view representation of a left side of a heart. A balloon 960, which is generally coupled to implant 924, may be inflated once implant 924 is positioned over guide wire 802. Balloon 960, once inflated, substantially fills space in left  
10 ventricle 720 between mitral valve 728 and a papillary muscle 964. Inflating balloon 960 enables the pressure within balloon 960 to effectively force implant 924 against fibrous tissue 970 of the fibrous ring around mitral valve 728. In one embodiment, balloon 960 is formed from an elastomeric material.

15 Once implant 924 is suitably positioned, a T-bar delivery catheter may be inserted through implant 924, as mentioned above with respect to Fig. 5. Although a T-bar delivery catheter is described as providing T-bars which are suitable for coupling implant 924 to fibrous tissue 970 associated with the fibrous ring around mitral valve 728, it should be understood that other methods may be used to couple  
20 implant 924 to tissue. Substantially any mechanism or device which may reliably hold tissue may be used. Suitable devices include, but are not limited to, anvil arrangements, staples, clips, barbs, and sutures.

Referring next to Fig. 10, one embodiment of a T-bar delivery catheter will be  
25 described in accordance with an embodiment of the present invention. A T-bar delivery catheter 1004 may be positioned over guide wire 802 and within implant 924. It should be appreciated that T-bar delivery catheter 1004 and implant 924 have not been drawn to scale. Within delivery catheter 1004 is a wire 1008 which carries a T-bar 1012. T-bar 1012 is coupled to an extension 1016 which may be used to  
30 effectively tie off T-bar 1012 such that T-bar 1012 holds implant 924 against fibrous tissue 970 around the mitral valve. Typically, a pointed or sharpened end 1020 of wire 1008 penetrates both implant 924 and fibrous tissue 970. Once end 1020 and T-

bar 1012 are both located above fibrous tissue 970, wire 1008 may be retracted, while T-bar 1012 remains above fibrous tissue 970, *i.e.*, on an atrial side of fibrous tissue 970. Retracting wire 1008 and, in one embodiment, delivery catheter 1004, entirely out of a patient enables an additional T-bar to be loaded onto wire 1008. Once an  
5 additional T-bar is positioned on wire 1008, wire 1008 may be reinserted into delivery catheter 1004, and delivery catheter 1004 may be used to enable another location along implant 924 to be essentially attached to fibrous tissue 970.

In general, the number of T-bars 1012 which may be used to create  
10 connections between implant 924 and fibrous tissue 970 may vary widely. By way of example, the use of approximately six or eight T-bars 1012 may be suitable, although fewer or more T-bars 1012 may be used as necessary. After all T-bars 1012 are in place with respect to implant 924, T-bars 1012 may be tightened by tying off extensions 1016 associated with T-bars 1012.

15 While T-bars 1012 create relatively intimate contact between implant 924 and fibrous tissue 970, in order to effectively shorten implant 924, *i.e.*, to provide treatment or therapy using implant 924, implant 924 is typically tensioned. That is, the size of mitral valve 728 may be reduced by tensioning implant 924. With  
20 reference to Figs. 11a and 11b, one method of providing tension to an implant will be described in accordance with an embodiment of the present invention. An implant 1124 is positioned under a mitral valve 1128, *i.e.*, in a left ventricle of a heart, and is held against mitral valve 1128 using coupling devices 1112 that effectively attach implant 1124 to fibrous tissue 1170. In the described embodiment, coupling devices  
25 1112 are T-bars, although it should be understood that other coupling devices, *e.g.*, staples or barbs, may be used in lieu of T-bars.

In order to reduce the size of mitral valve 1128, which is stretched such that a gap 1130 is evident between a posterior leaflet 1132 and an anterior leaflet 1134, a  
30 tensioning element 1140 which is inserted within implant 1124 may be tensioned to shorten an arc length of implant 1124. Generally, tensioning element 1140 may be inserted within implant 1134 using a catheter after implant 1134 is inserted into the

left ventricle. Alternatively, tensioning element 1140 may be preloaded in implant 1134. As shown, tensioning element 1140 is a string which may be pulled and ultimately tied off to effectively reduce the arc length associated with the curved outer edge of mitral valve 1128. Pulling on and tying off tensioning element 1140 may be  
5 achieved through the use of a catheter 1150 inserted within implant 1134.

When tension element 1140 is tensioned, implant 1124 effectively collapses onto itself, or is shortened. As previously mentioned, implant 1124 may be formed from a spring-like structure that is covered by a mesh. The spring-like structure is an  
10 elongated body may be collapsed onto itself or shortened when tension is applied. Hence, as shown in Fig. 11b, the arc length associated with mitral valve 1128 may be reduced, *e.g.*, by a two-to-one ratio. Reducing the arc length associated with mitral valve 1128 allows gap 1130 to be greatly reduced. In one embodiment, gap 1130 effectively disappears such that there is no leakage of mitral valve 1128.

15

In one embodiment, implant 1124 is arranged to bend and to collapse onto itself such that a radius of curvature associated with implant 1124 may vary. That is, applying tension to implant 1124 allows the radius of curvature of implant 1124 to be reduced. As implant 1124 is coupled to fibrous tissue 1170 in proximity to mitral  
20 valve 1134, when the radius of curvature of implant 1124 is reduced, the size of mitral valve 1134 is also reduced.

It should be appreciated that the configuration of tensioning element 1140 be different than shown herein. While tensioning element 1140 may be a string or a  
25 similar element which may be tied off, tensioning element 1140 may also be substantially any element on which tension may be applied by pulling. Another particularly suitable tension element is a cable wrap or "zip tie," which is generally an element that may be looped onto itself and then tightened by pulling, *e.g.*, through the use of a catheter such as catheter 1150 of Fig. 11a. Releasing such an element after  
30 pulling generally does not significantly alter the tension associated with the element.



Tensioning element 1140, in cooperation with an adjustable, or collapsible, implant 1124 allows implant 1124 to be continually adjusted as needed. By way of example, if a patient requires a readjustment of implant 1124 at some point after the initial catheter-based annuloplasty, the patient may undergo a relatively simple  
5 catheter-based procedure designed to alter the tension in implant 1124. Further, the need to select an implant 1124 for use based upon the size of a particular implant 1124 may be reduced, as an implant 1124 of a single size may be adjusted when already implanted to properly reduce the size of a stretched mitral valve 1128.

10 Once implant 1124 is properly adjusted, a patient may be placed on anticoagulant therapy until mitral tissue has begun to successfully grow around and into implant 1124. When tissue growth has reached a desired level, the new tissue may then effectively support implant 1124, and the patient may generally cease anticoagulant therapy. As catheter-based annuloplasty is not an open surgery and is  
15 considered to be relatively non-invasive, the recovery time from catheter-based annuloplasty is relatively short when compared to the recovery time required by conventional surgical annuloplasty procedures.

With reference to Fig. 12, the performance of an annuloplasty procedure using  
20 a catheter-based system will be described in accordance with an embodiment of the present invention. Once a patient is prepared, *e.g.*, sedated, an annuloplasty procedure 504 may begin with the insertion of a delivery tube and a J-catheter into the left ventricle of the heart of the patient. The delivery tube and the J-catheter may be inserted into the body of the patient through the femoral artery, and threaded through  
25 the femoral artery and the aorta into the left ventricle of the heart. Generally, the J-catheter is positioned within the delivery tube. One embodiment of the delivery tube and a J-catheter were described above with respect to Figs. 6a and 6b. As will be appreciated by those skilled in the art, the delivery tube and the J-catheter are typically each threaded through the aortic valve to reach the left ventricle.

30

Once the delivery tube and the J-catheter are positioned within the left ventricle, a gutter catheter may be extended through the J-catheter in step 512. As

was discussed above with reference to Figs. 7a-c, the gutter catheter is arranged to effectively run against a gutter of the wall of the left ventricle substantially immediately under the mitral valve. Specifically, the gutter catheter may be positioned in the space in the left ventricle between the mitral valve and the muscoli  
5 papillares, or papillary muscles. The gutter catheter often has a tip that is steerable and flexible. In one embodiment, the tip of the gutter catheter may be coupled to an inflatable balloon. The J-catheter serves, among other purposes, the purpose of allowing the gutter catheter to be initially oriented in a proper direction such that the gutter catheter may be positioned along the wall of the left ventricle.

10

In step 516, a guide wire with an anchoring feature may be delivered through the gutter catheter, *e.g.*, through a lumen or opening in the gutter catheter. The guide wire is delivered through the gutter catheter such that it follows the contour of the gutter catheter against the wall of the left ventricle. After the guide wire is delivered,  
15 the anchoring feature of the guide wire is anchored on the wall of the left ventricle in step 520. Anchoring the guide wire, or otherwise implanting the guide wire, on the wall of the left ventricle enables the guide wire to maintain its position within the left ventricle.

20

The J-catheter and the gutter catheter are pulled out of the left ventricle through the femoral artery in step 524, leaving the guide wire anchored within the left ventricle, as was discussed above with respect to Fig. 8. Once the J-catheter and the gutter catheter are removed from the left ventricle, an implant which may be coupled to a substantially deflated balloon is inserted into the left ventricle using the guide  
25 wire as a guide track in step 528. In other words, an implant that is intended to be coupled to the mitral valve is positioned in the left ventricle under the mitral valve, *i.e.*, on a ventricular side of the mitral valve. One suitable implant was described above with respect to Fig. 9a. In one embodiment, the implant may be inserted into the left ventricle using a catheter which may be retracted once the implant is  
30 positioned under the mitral valve in contact with the fibrous tissue around the mitral valve.

After the implant and the balloon are inserted in the left ventricle, the balloon is inflated in step 532. Inflating the elastomeric balloon at a relatively modest pressure using, for example, an air supply coupled to the balloon through the implant, serves to cause the implant to be pressed up against the fibrous tissue around the mitral valve. Generally, the inflated balloon substantially occupies the space between the mitral valve and the papillary muscles. In one embodiment, more than one balloon may be used to position the implant against the fibrous tissue around the bottom of the mitral valve.

10 A T-bar delivery catheter is inserted through the implant in step 536, once the balloon is inflated in step 532. The T-bar delivery catheter effectively delivers T-bars, or similar mechanisms, which are arranged to attach or otherwise couple the implant to an annulus of the mitral valve, e.g., the fibrous tissue of the skeleton around the mitral valve. In step 540, connections are created between the implant and substantially any suitable tissue near the mitral valve to effectively attach the implant to the tissue. The connections may be created by extending sharpened wires which carry elements such as T-bars through the implant and the tissue, then retracting the sharpened wires, and locking the T-bars in place, as discussed above with respect to Fig. 10.

20 Once a desired number of connections, e.g., six connections, are made between the implant and the tissue, then the balloon may be deflated and removed from the left ventricle in step 548. It should be understood that since the implant is effectively connected to tissue around the mitral valve, deflating the balloon does not cause the position of the implant to be significantly moved. After the balloon is deflated, the T-bar delivery catheter is removed from the left ventricle in step 522. In step 556, the guide wire may be removed. The implant is then typically shortened in step 558, as for example by providing tension to the implant. As will be appreciated by those skilled in the art, shortening the implant involves contracting the mitral valve or, more specifically, the posterior leaflet of the mitral valve. Although the implant may be shortened in substantially any suitable manner, in one embodiment, the implant may be shortened by tightening a string or a cord associated with the implant

to effectively reduce the arc length associated with the implant, *e.g.*, by a two-to-one ratio. Once the implant is successfully shortened, the delivery tube may be removed in step 560. After the delivery tube is removed, the annuloplasty procedure is completed.

5

It should be appreciated that implanting an implant in tissue near the mitral valve, then shortening the implant, is just one method of treating mitral valve leakage in a minimally invasive manner using a catheter-based system. Another method, which will be described below with respect to Figs. 13a and 13b, involves accessing  
10 the mitral valve through the aorta and the left ventricle, and implanting a clip element which serves to effectively pinch together the anterior leaflet and the posterior leaflet of the mitral valve to reduce leakage. Fig. 13a is a schematic cut-away representation of a left ventricle of the heart in which a catheter that is suitable for use in accessing a mitral valve in accordance with a second embodiment of the present invention is  
15 positioned. Fig. 13b is a cross-sectional representation of the left ventricle and the catheter of Fig. 13a. A catheter 1304 is inserted into a left ventricle 1314 through an aortic valve 1310. Catheter 1304, which may be steerable and flexible, has a curved orientation such that catheter 1304 may pass between cordae tendonae 1326 that are coupled to papillary muscles 1322 and mitral valve 1340. That is, catheter 1304 is  
20 shaped to pass through a plane defined by papillary muscles 1322, as well as cordae tendonae 1326, to reach a posterior leaflet "side" of mitral valve 1340.

As shown, catheter 1304 does not follow the contour of a wall 1318 of left ventricle 1314, and is still positioned such that a portion of catheter 1304 is positioned  
25 in a region of left ventricle 1314 between mitral valve 1340, cordae tendonae 1326, papillary muscles 1322, and wall 1318. Hence, catheter 1304 is able to directly access a posterior leaflet of mitral valve 1340 substantially directly. A catheter 1304 which, in one embodiment, accesses a gutter portion of left ventricle 1314 may be easier to fabricate and to actively control than a catheter assembly which includes a J-  
30 catheter and a gutter catheter, *e.g.*, J-catheter 608 and gutter catheter 704 of Fig. 7a, as catheter 1304 generally does not need to be manipulated with many direction changes. Instead, catheter 1304 may be formed to include either a curved end portion, as shown

in Fig. 13b, or a v-shaped end portion which both enable an end portion of catheter 1304 to access the portion of left ventricle 1314 that is positioned substantially immediately under mitral valve 1340.

5           A tip portion of catheter 1304 may be directed against mitral valve 1340, thereby facilitating the ability to place a tissue anchor or clip element which may act to pinch an anterior leaflet against a posterior leaflet. Fig. 13c is a schematic representation of a clip element positioned with respect to a posterior leaflet and an anterior leaflet of a mitral valve in accordance with a second embodiment of the  
10           present invention. It should be appreciated that the elements in Fig. 13c have not been drawn to scale for purposes of discussion. A clip 1380, which may be formed from a material such as steel, may be coupled to an anterior leaflet 1362 and a posterior leaflet 1366 of a mitral valve using catheter 1304 of Figs. 13a and 13b. Clip 1380, which passes between cordae tendonae 1326 associated with anterior leaflet 1362 and  
15           cordae tendonae 1326 associated with posterior leaflet 1366, may be coupled to anterior leaflet 1362 and posterior leaflet 1366 using, for example, T-bar arrangements 1390.

          By pinching together anterior leaflet 1362 and posterior leaflet 1366, the  
20           leakage through a gap (not shown) between anterior leaflet 1362 and posterior leaflet 1366 may be reduced. While the presence of clip 1380 may result in a patient having to undergo anticoagulant therapies, the placement of clip 1380 in lieu of an implant such as implant 924 of Fig. 9b may minimize the amount of time associated with a leakage correction process.

25           Although only a few embodiments of the present invention have been described, it should be understood that the present invention may be embodied in many other specific forms without departing from the spirit or the scope of the present invention. By way of example, methods of introducing an implant into the left  
30           ventricle to correct for mitral valve leakage, or mitral valve insufficiency, may be applied to introducing implants which correct for leakage in other valves. For

instance, the above-described procedure may be adapted for use in repair a leaking valve associated with a right ventricle.

5 While connecting an implant to fibrous tissue associated with the mitral valve of the heart has generally been described, the implant may be connected to other types of tissue which are near, around, in proximity to, or include the mitral valve. Other tissues to which an implant may be connected include tissues associated with the myocardium, or tissues associated with the wall of the left ventricle. In one embodiment, the implant may be substantially directly connected to the leaflets of the  
10 mitral valve.

In general, methods of accessing a left ventricle through the aorta may be applied to procedures other than annuloplasty. The left ventricle may be accessed to perform mapping or ablation therapies, or to stabilize a patient suffering from an acute  
15 valve failure, *e.g.*, by filling space in the left ventricle by inflating a balloon. Also, a balloon, either steady state or pulsatile, may be used to increase the ejection fraction associated with the left ventricle. The left ventricle may also be accessed in order to access the left atrium through the mitral valve. Specifically, the smooth portion of the left ventricle, *e.g.*, the gutter, may be accessed en route to accessing the left atrium. It  
20 should be appreciated that accessing the gutter may be used in conjunction with access routes via other channels to the heart such as a coronary sinus and a transseptal approach to the left atrium.

While a balloon may be inflated within a left ventricle such that the balloon is  
25 effectively trapped under the posterior leaflet of a mitral valve to treat sudden heart failure. The balloon may remain positioned in the left ventricle until surgery is performed on the heart, at which time the balloon may be removed. In one embodiment, such a balloon may be arranged to be filled with blood that clots off, thereby enabling the balloon to become what is effectively a permanent structure in  
30 the left ventricle that reduces mitral regurgitation.

Access to the left ventricle may also facilitate the use of a camera within left ventricle. For example, a camera may be fed into the left ventricle on the tip of a catheter-like device to enable the interior of the left ventricle to be viewed to identify any anomalies which may be present in the left ventricle. It should be appreciated  
5 that such a camera may also be passed into the coronary sinus.

Rather than implanting an implant to correct for mitral valve insufficiency using a catheter-based approach, a series of local plications to the mitral valve may be used to achieve annuloplasty. By way of example, a catheter or other device that is  
10 suitable for creating local plications may be located along the wall of a left ventricle beneath the mitral valve. Local plications may be created by elements which engage fibrous tissue and close upon themselves such that tissue is engaged. Alternatively, a one-way tensioning device may be used to effectively pull in on the local plications, *e.g.*, elements, such that the arc length of the mitral valve is effectively reduced.

15 Local plications may generally be created through the use of staple elements which engage each other once they penetrate the fibrous tissue, or hook-like elements. It should be appreciated, however, that in other embodiments, suture type materials may be used to create local plications.

20 While an implant which may effectively collapse onto itself, *e.g.*, be shortened, when tension is applied is suitable for use in a catheter-based annuloplasty as described above, it should be appreciated that such an implant is suitable for use in a variety of different annuloplasty procedures. For instance, the implant may be used  
25 in a conventional, surgical annuloplasty procedure since its use may enable a surgeon to continuously adjust the amount by which the arc length of a mitral valve may be reduced.

An implant has generally been described as having a shape which is similar to  
30 that of a horseshoe ring. Implants of other shapes may generally be implanted within a heart to correct for mitral valve insufficiency. By way of example, an implant which has a curved shape that does not follow substantially the entire arc length of a

mitral valve may be implanted without departing from the spirit or the scope of the present invention. Such an implant may generally cover a larger area than would be covered by a local plication.

5           It should be understood that although a guide wire has been described as including an anchoring tip to anchor the guide wire to a wall of the left ventricle, a guide wire may be anchored with respect to the left ventricle in substantially any suitable manner. By way of example, a guide wire may include an anchoring feature which is located away from the tip of the guide wire. In addition, a guide wire may  
10   more generally be any suitable guiding element which is configured to facilitate the positioning of an implant.

          An elastomeric balloon has been described as being suitable for use in effectively forcing an implant against a surface to which the implant is to be  
15   connected. In lieu of an elastomeric balloon, substantially an expanding structure may be used to push the implant against a surface. By way of example, an expanding metal structure which is expandable from a closed position into an open position may be used to provide pressure or force on an implant.

20           While access to the gutter of the left ventricle has been described as being associated with a minimally invasive catheter annuloplasty procedure, it should be understood that the gutter of the left ventricle may also be accessed, *e.g.*, for an annuloplasty procedure, as a part of a surgical procedure. For instance, the aorta of a heart may be accessed through an open chest surgical procedure before a catheter is  
25   inserted into the aorta to reach the left ventricle. Alternatively, an implant may be introduced on a ventricular side of a mitral valve through a ventricular wall which is accessed during an open chest surgical procedure.

          The steps associated with performing a catheter-based annuloplasty may be  
30   widely varied. Steps may generally be added, removed, reordered, and altered without departing from the spirit or the scope of the present invention. Therefore, the present examples are to be considered as illustrative and not restrictive, and the



invention is not to be limited to the details given herein, but may be modified within the scope of the appended claims.

## WHAT IS CLAIMED IS:

1. A method for performing a procedure on a mitral valve of a heart, the method comprising:
  - 5 inserting at least one implant into a left ventricle of the heart;  
positioning the at least one implant with respect to the mitral valve, wherein positioning the implant includes orienting the implant in the left ventricle substantially below the mitral valve; and  
attaching the implant to tissue located near the mitral valve.
- 10 2. A method as recited in claim 1 further including:  
reducing an arc length of the implant, wherein reducing the arc length of the implant substantially reduces an arc length associated with the mitral valve.
- 15 3. A method as recited in claim 1 wherein inserting the implant into the left ventricle includes:  
introducing the implant into an aorta; and  
passing the implant through an aortic valve interposed between the aorta and the left ventricle.
- 20 4. A method as recited in claim 3 further including:  
introducing a guide element into the left ventricle, the guide element being configured to be positioned in the left ventricle between a plane of the mitral valve and a plane associated with papillary muscles of the heart, wherein inserting the  
25 implant into the left ventricle includes positioning the implant such that the implant uses the guide element as a track.
5. A method as recited in claim 4 further including:  
removing the guide element from the left ventricle after attaching the implant  
30 to the tissue.

6. A method as recited in claim 4 wherein introducing the guide element into the left ventricle includes:

introducing a first catheter assembly into the aorta, the first catheter assembly including an angled catheter, and a gutter catheter, wherein the angled catheter

5 substantially carries the gutter catheter, the angled catheter being arranged to facilitate positioning of the gutter catheter;

positioning the gutter catheter beneath the mitral valve between the plane of the mitral valve and the plane associated with the papillary muscles, wherein

10 positioning the gutter catheter includes positioning the gutter catheter along a wall of the left ventricle; and

inserting the guide element into a lumen of the gutter catheter.

7. A method as recited in claim 6 wherein introducing the guide element into the left ventricle further includes:

15 anchoring the guide element against the wall.

8. A method as recited in claim 4 wherein attaching the implant to the tissue includes:

20 introducing a catheter into the left ventricle using the guide element as a track, wherein the catheter includes at least one pointed wire, the pointed wire including a tip section, the pointed wire further being configured to carry a coupling element, the tip section being configured for insertion into the implant and the tissue;

25 pushing the tip section through the implant and the tissue, wherein pushing the tip section through the implant and the tissue positions at least a part of the coupling element on an atrial side of the tissue; and

retracting the tip section from the implant and the tissue, wherein retracting the tip section causes the coupling element to substantially couple the implant with the tissue.

30 9. A method as recited in claim 8 wherein the coupling element is a T-bar.

10. A method as recited in claim 3 further including:

introducing a guide element into the left ventricle, the guide element being configured to be positioned in the left ventricle in a region of the left ventricle substantially bounded by leaflets of the mitral valve, the papillary muscles of the heart, a ventricular wall, and cordae tendonae, wherein inserting the implant into the  
5 left ventricle includes positioning the implant such that the implant uses the guide element as a track.

11. A method as recited in claim 1 further including:  
adjusting an arc length of the implant.  
10
12. A method as recited in claim 1 wherein the tissue is fibrous tissue.
13. A method for performing annuloplasty on a mitral valve of a heart, the method comprising:  
15 inserting a first catheter assembly into a left ventricle through an aorta of the heart and an aortic valve of the heart;  
positioning a guide element along a wall of the left ventricle beneath the mitral valve using the first catheter assembly;  
positioning at least one implant in the left ventricle beneath the mitral valve  
20 using the guide element as a guide; and  
connecting the at least one implant to tissue near the mitral valve.
14. A method as recited in claim 13 wherein the implant includes a shortening means, and the method further includes:  
25 shortening the implant using the shortening means, wherein shortening the implant substantially reduces an arc length of the mitral valve.
15. A method as recited in claim 13 wherein the first catheter assembly includes a first catheter and a second catheter, the second catheter being located at least partially  
30 within the first catheter, the first catheter being arranged to facilitate the positioning of the second catheter along the wall of the left ventricle, and wherein positioning the guide element along the wall includes:

inserting the guide element through the second catheter; and  
anchoring the guide element against the wall.

16. A method as recited in claim 15 further including:  
5 removing the first catheter and the second catheter from the left ventricle; and  
inserting a third catheter into the left ventricle, the third catheter configured to  
carry the implant and to use the guide element as a guide.
17. A method as recited in claim 13 wherein connecting the implant to the tissue  
10 near the mitral valve includes:  
inserting a fourth catheter into the left ventricle, the fourth catheter being  
configured to carry a first connection element; and  
inserting the first connection element through the implant and the tissue such  
that the implant and the tissue are coupled by the first connection element.  
15
18. A method as recited in claim 17 wherein the fourth catheter is further  
configured to carry a second connection element, the method further including:  
inserting the second connection element through the implant and the tissue  
such that the implant and the tissue are coupled by the second connection element.  
20
19. A method as recited in claim 17 wherein positioning the implant in the left  
ventricle beneath the mitral valve using the guide element further includes:  
inserting at least one balloon into the left ventricle; and  
inflating the balloon, wherein inflating the balloon positions the implant  
25 generally against the mitral valve.
20. A method as recited in claim 17 wherein positioning the implant in the left  
ventricle beneath the mitral valve using the guide element further includes:  
inserting at least one expandable element into the left ventricle; and  
30 expanding the expandable element, wherein expanding the expandable  
element positions the implant generally against the mitral valve.

21. A method for accessing a left ventricle of a heart, the method comprising  
introducing an elongated body into an aorta of the heart;  
passing at least a portion of the elongated body through an aortic valve  
positioned between the aorta and the left ventricle; and  
5 positioning the portion of the elongated body in the left ventricle.
22. A method as recited in claim 21 wherein locating the portion of the elongated  
body in the left ventricle includes positioning the portion of the elongated body  
between a plane associated with a mitral valve of the heart and a plane associated with  
10 papillary muscles of the left ventricle.
23. A method as recited in claim 22 wherein the elongated body is an implant, and  
locating the portion of the elongated body in the left ventricle further includes  
positioning the implant substantially against tissue near the mitral valve.  
15
24. A method as recited in claim 22 wherein the elongated body is a catheter.
25. A method as recited in claim 24 wherein the catheter is arranged to provide at  
least one plication in the tissue near the mitral valve.  
20
26. A method as recited in claim 21 wherein locating the portion of the elongated  
body in the left ventricle includes positioning the portion of the elongated body  
between a plane associated with a mitral valve of the heart, a plane associated with  
papillary muscles of the left ventricle, cordae tendoneae of the left ventricle, and a wall  
25 of the left ventricle.
27. A method as recited in claim 26 wherein the elongated body is an implant, and  
locating the portion of the elongated body in the left ventricle further includes  
positioning the implant substantially against tissue near the mitral valve.  
30
28. A method as recited in claim 26 wherein the elongated body is a catheter.

29. A method as recited in claim 28 wherein the catheter is arranged to provide at least one plication in the tissue near the mitral valve.
30. A method as recited in claim 21 further including:  
5 introducing an expandable element into the aorta, wherein the expandable element is substantially unexpanded;  
positioning the expandable element in the left ventricle; and  
expanding the expandable element, wherein expanding the expandable element causes the portion of the elongated body to contact a target region of the  
10 heart.
31. A method as recited in claim 30 wherein the target region of the heart is tissue near the a mitral valve of the heart.
- 15 32. A method for performing annuloplasty, the method comprising:  
accessing a left ventricle of a heart to provide an implant to the left ventricle;  
and  
coupling the implant to tissue near a mitral valve of the heart, wherein the implant is coupled to a ventricular side of the mitral valve.  
20
33. A method as recited in claim 32 further including:  
shaping the implant, wherein shaping the implant substantially reduces an arc length associated with the mitral valve.
- 25 34. A method as recited in claim 33 wherein shaping the implant includes substantially reducing an arc length of the implant by providing tension to the implant.
- 30 35. A method as recited in claim 32 wherein accessing the left ventricle includes inserting an elongated body into the left ventricle through an aorta and an aortic valve of the heart.

36. A method as recited in claim 35 wherein providing the elongated body into the left ventricle includes inserting the elongated body into the left ventricle between a plane associated with the mitral valve and a plane associated with papillary muscles of the heart.
- 5
37. A method as recited in claim 35 wherein providing the elongated body into the left ventricle includes inserting the elongated body into a region of the left ventricle substantially defined between a plane associated with the mitral valve, a plane associated with papillary muscles of the heart, a wall of the left ventricle, and cordae  
10 tendonae of the heart.
38. A device for use in an annuloplasty procedure, the device comprising:  
a member, the member being arranged to be substantially shortened with respect to itself when tension is applied to the member;  
15 a mesh, the mesh being arranged over the member; and  
a tensioning element, the tensioning element being configured to apply tension to the member, wherein when the device is coupled to tissue surrounding a mitral valve of a heart, the tensioning element is configured to cause the device to reduce an arc length associated with the mitral valve.
- 20
39. A device according to claim 38 wherein the device is suitable for being positioned on a ventricular side of the mitral valve.
40. A device according to claim 39 wherein the tensioning element is  
25 continuously adjustable to alter the tension applied to the member.
41. A device according to claim 39 wherein the tensioning element is at least partially located within the member.
- 30
42. A device according to claim 39 further including:  
a coupler, the coupler being arranged to extend through the member and the mesh, the coupler further being arranged to couple the device to the tissue.



43. A device according to claim 42 wherein the coupler is a T-bar.
44. A device for use in an annuloplasty procedure, the device comprising:  
5 a collapsible member, wherein the collapsible member is movable between an extended position for insertion into a left ventricle through a catheter and a short position; and  
a shortening device, the shortening device being operable to move the compressible member between the extended position and the short position, wherein  
10 the device is positioned to reduce an opening of a mitral valve when the device is in the short position.
45. A device according to claim 44 further including:  
a mesh covering, the mesh covering extending over at least a portion of the  
15 compressible member.
46. A device according to claim 44 wherein the device is suitable for being coupled to tissue near the mitral valve.
- 20 47. A device according to claim 46 further including:  
a coupler, the coupler being configured to extend through the structure and the mesh, the coupler further being arranged to couple the device to the tissue.
48. A system for performing annuloplasty on a mitral valve of a heart, the system  
25 comprising:  
a catheter assembly configured for insertion through an aorta of the heart into a left ventricle of the heart to reach a region of the left ventricle substantially below the mitral valve;  
a guide element shaped for insertion into the catheter assembly, the guide  
30 element having an anchorable feature; and

an implant, the implant being shaped for insertion over the guide element into the left ventricle substantially below the mitral valve, wherein the implant is configured to be connected to tissue of the heart.

- 5     49.     A system according to claim 48 wherein the catheter assembly includes a delivery tube and a gutter catheter, the gutter catheter being positioned at least partially within the delivery tube, wherein a portion of the gutter catheter is configured to be positioned substantially within a region of the left ventricle defined between a plane associated with the papillary muscles of the left ventricle and a plane  
10     associated with the mitral valve.

50.     A system according to claim 49 wherein the guide element is shaped for insertion into a lumen of the gutter catheter.

- 15     51.     A system according to claim 48 wherein the catheter assembly includes a delivery tube and a gutter catheter, the gutter catheter being positioned at least partially within the delivery tube, wherein a portion of the gutter catheter is configured to be positioned substantially within a region of the left ventricle defined between a plane associated with the papillary muscles of the left ventricle, a plane  
20     associated with the mitral valve, cordae tendonae of the left ventricle, and a wall of the left ventricle.

52.     A system according to claim 48 further including:  
a delivery catheter, the connection catheter configured to provide a connection  
25     element, wherein the connection element is configured to connect the implant to the tissue.

53.     A system according to claim 52 wherein the tissue is located near the mitral valve.  
30

54.     A system according to claim 48 wherein the catheter assembly is at least partially formed from at least one of a nylon material and a urethane material.

55. A system according to claim 53 wherein the tissue is fibrous tissue.
56. A system according to claim 51 wherein the implant includes a shortening  
5 element, the shortening element being arranged to shorten an arc length associated  
with the implant, wherein shortening the arc length associated with the implant  
reduces an arc length associated with a posterior leaflet of the mitral valve.
57. A system according to claim 51 wherein the implant is configured to have a  
10 shortened state and an unshortened state, wherein when the implant is inserted over  
the guide element, the implant is in the unshortened state, and wherein when the arc  
length associated with the implant is shortened, the implant is in the shortened state.
58. A system according to claim 48 wherein the guide element is formed from one  
15 of a stainless steel material and a shape memory material.

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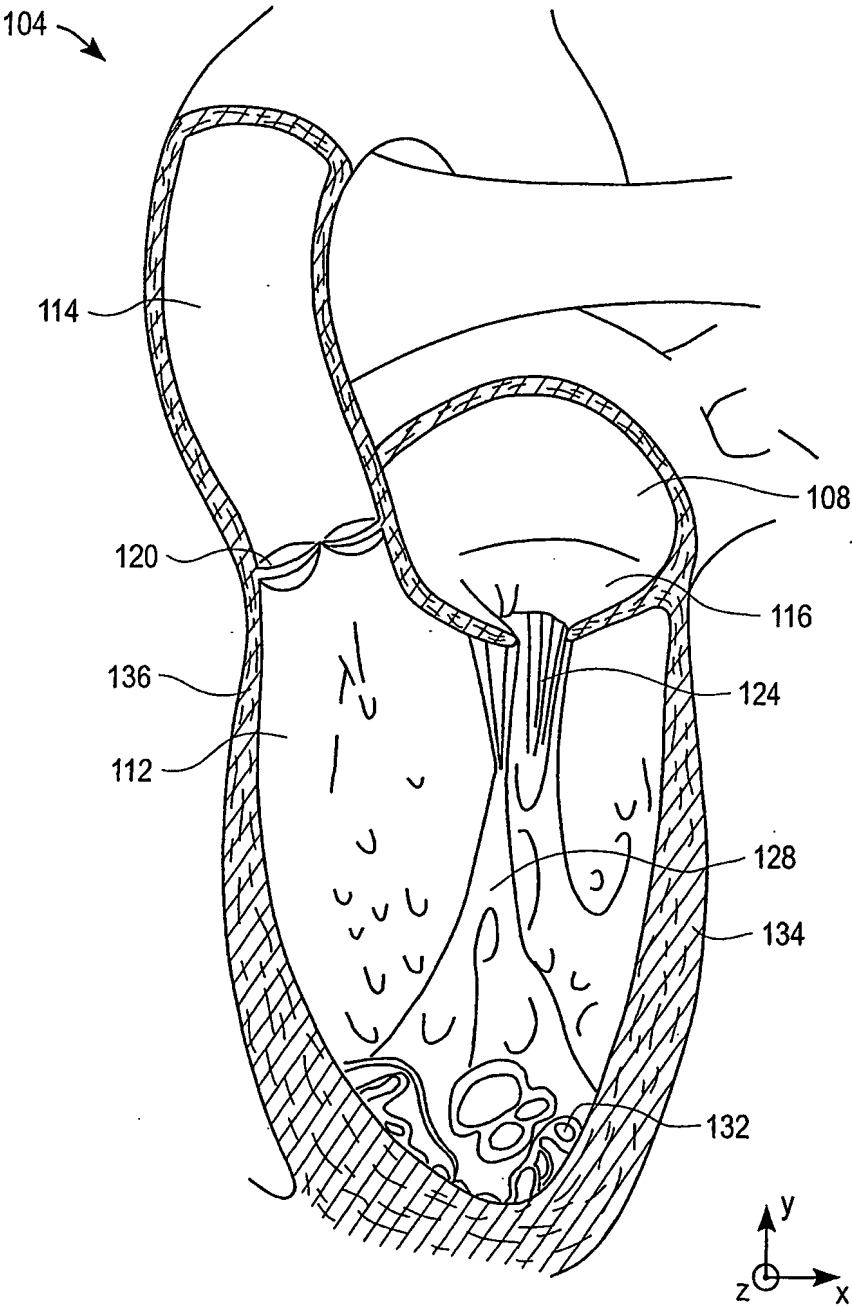


FIG. 1

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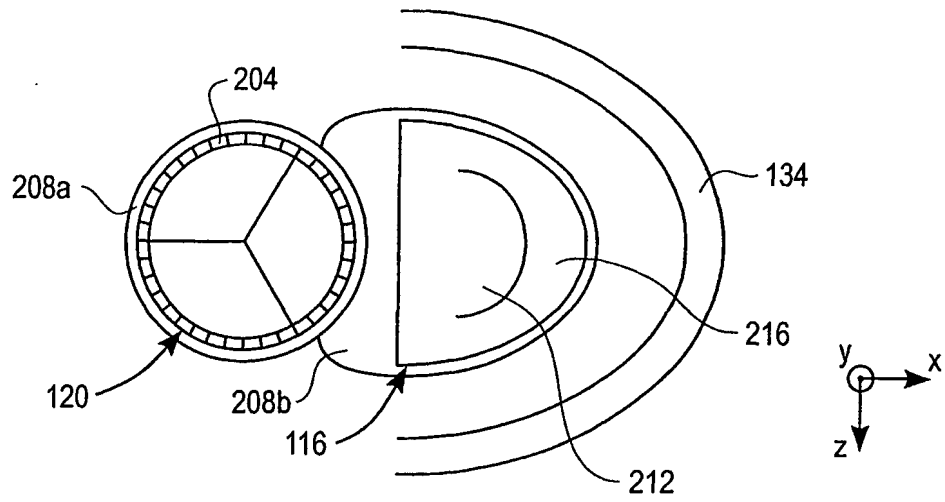


FIG. 2a

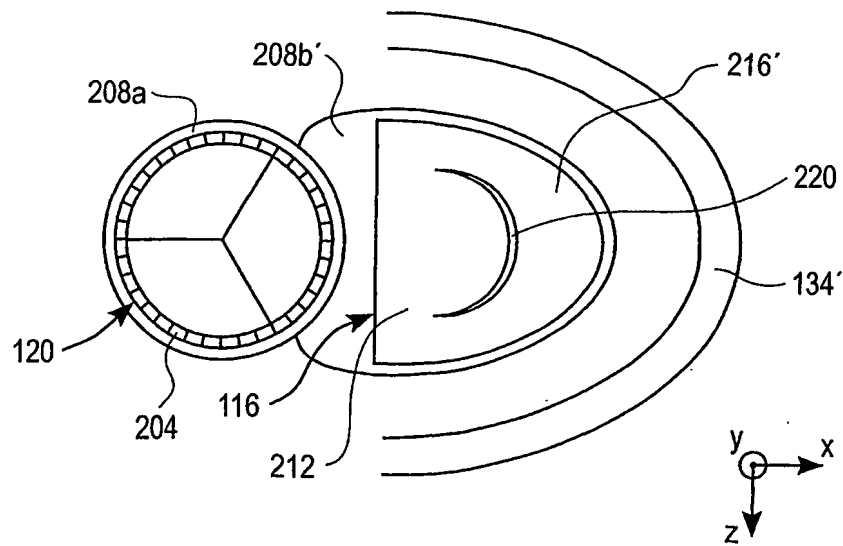


FIG. 2b

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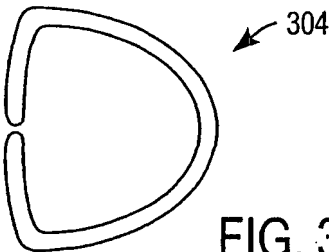


FIG. 3

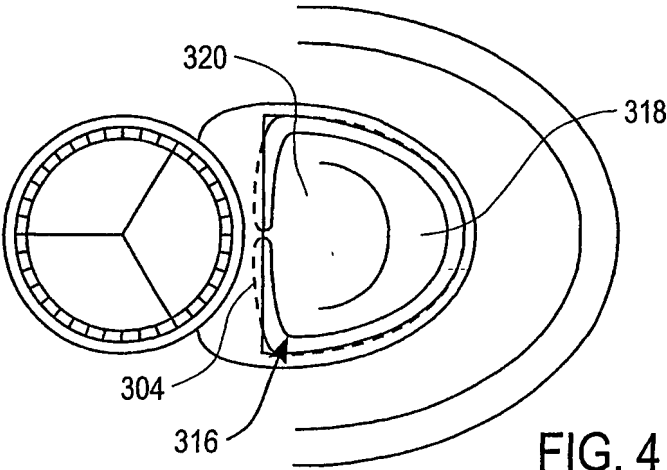


FIG. 4

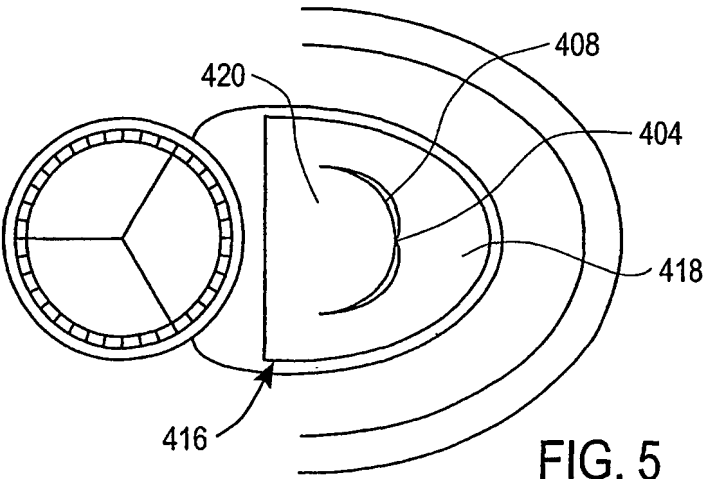


FIG. 5

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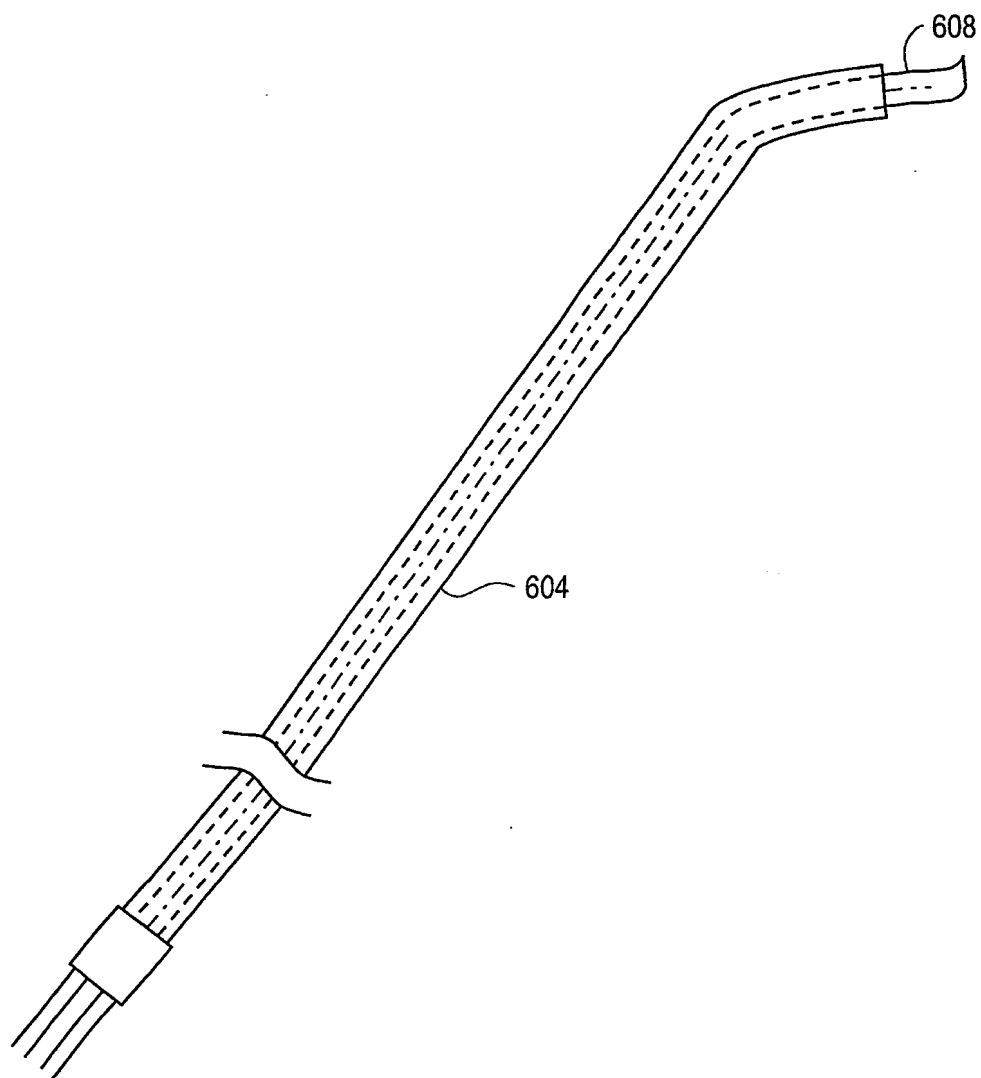


FIG. 6a

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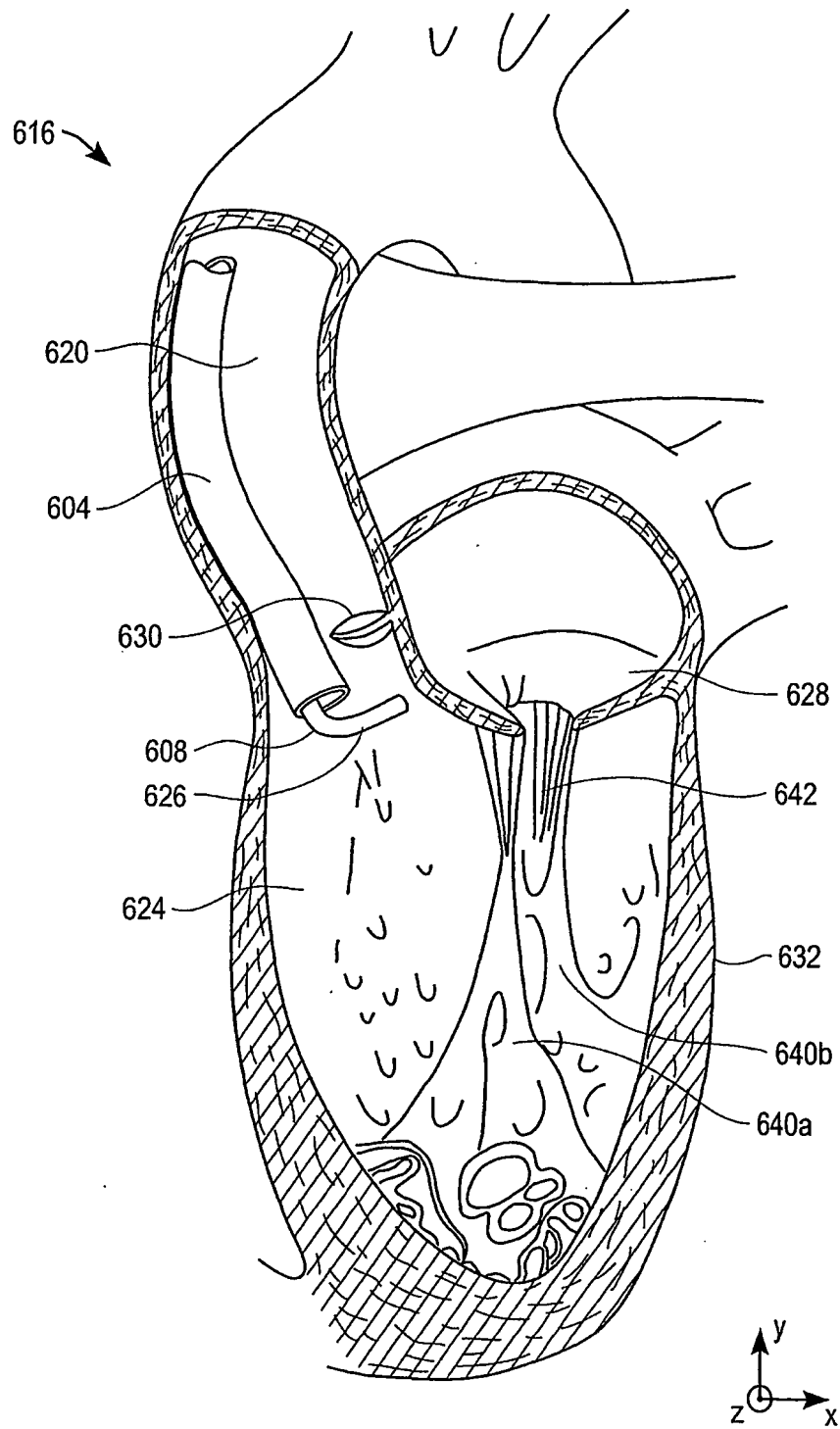
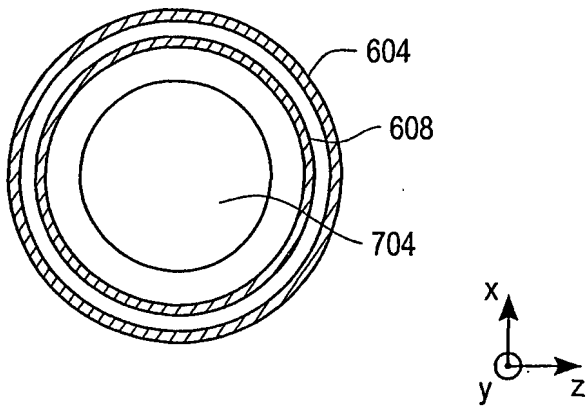
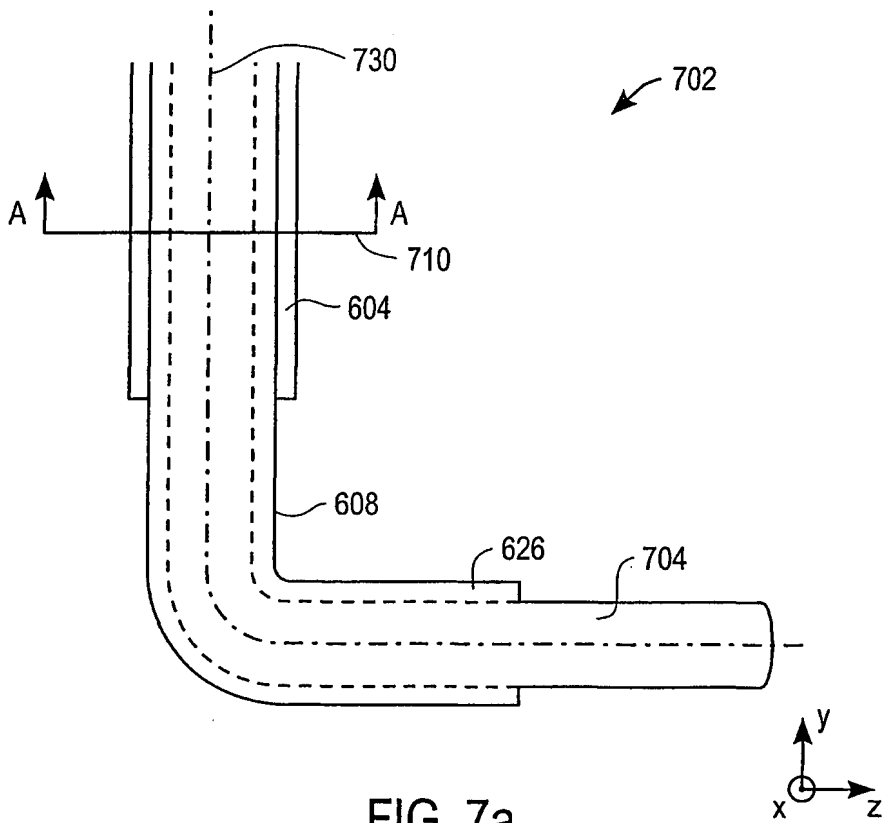


FIG. 6b



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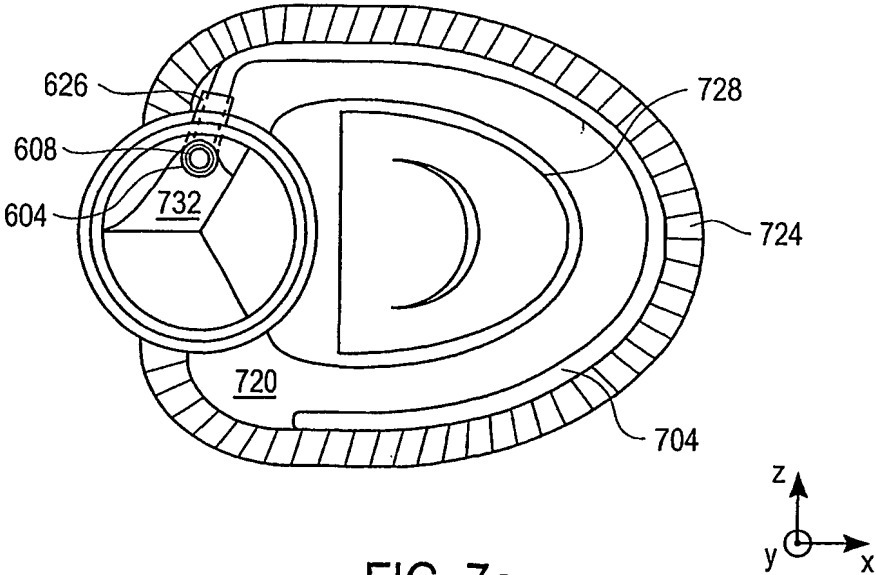


FIG. 7c

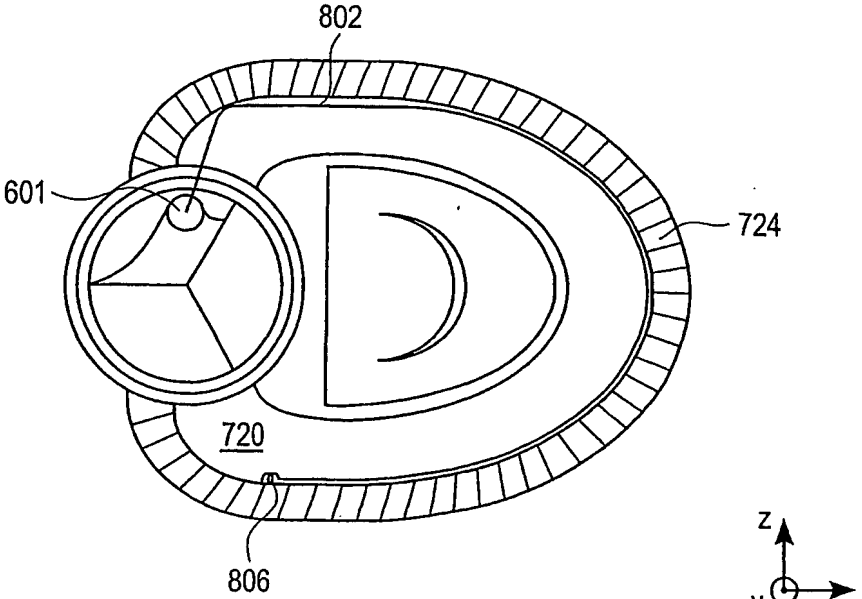
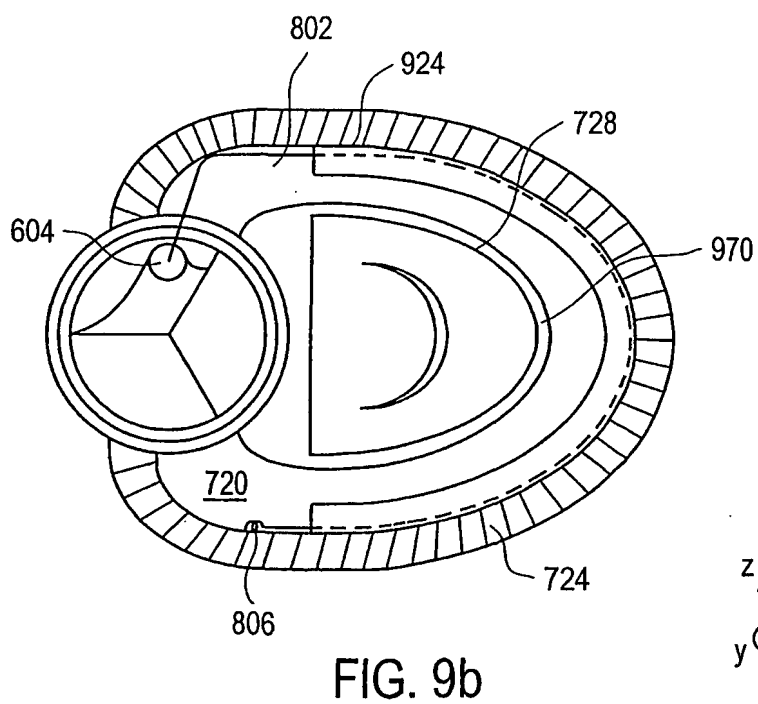
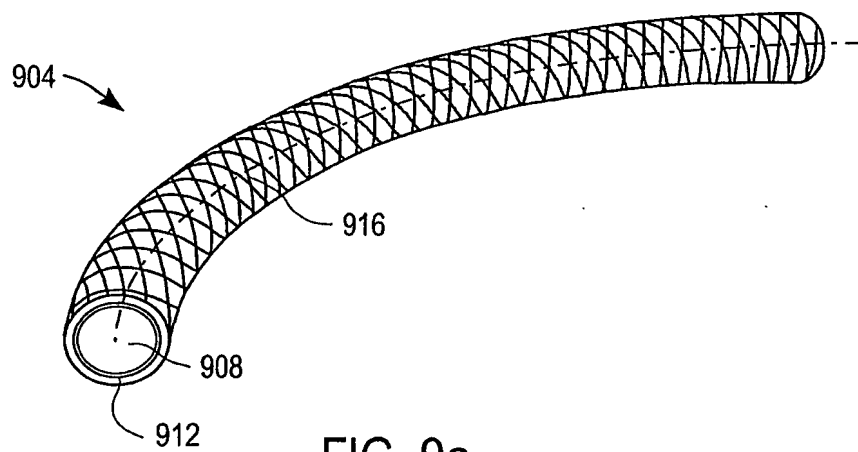


FIG. 8

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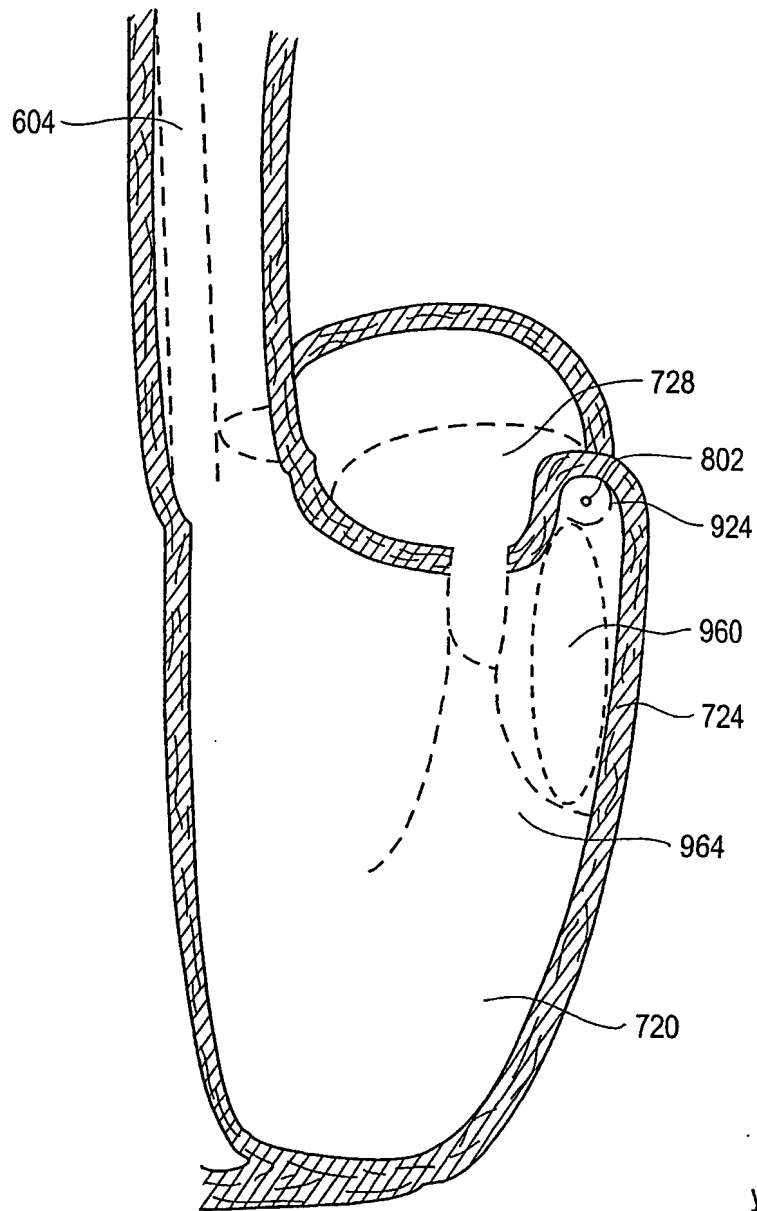


FIG. 9c

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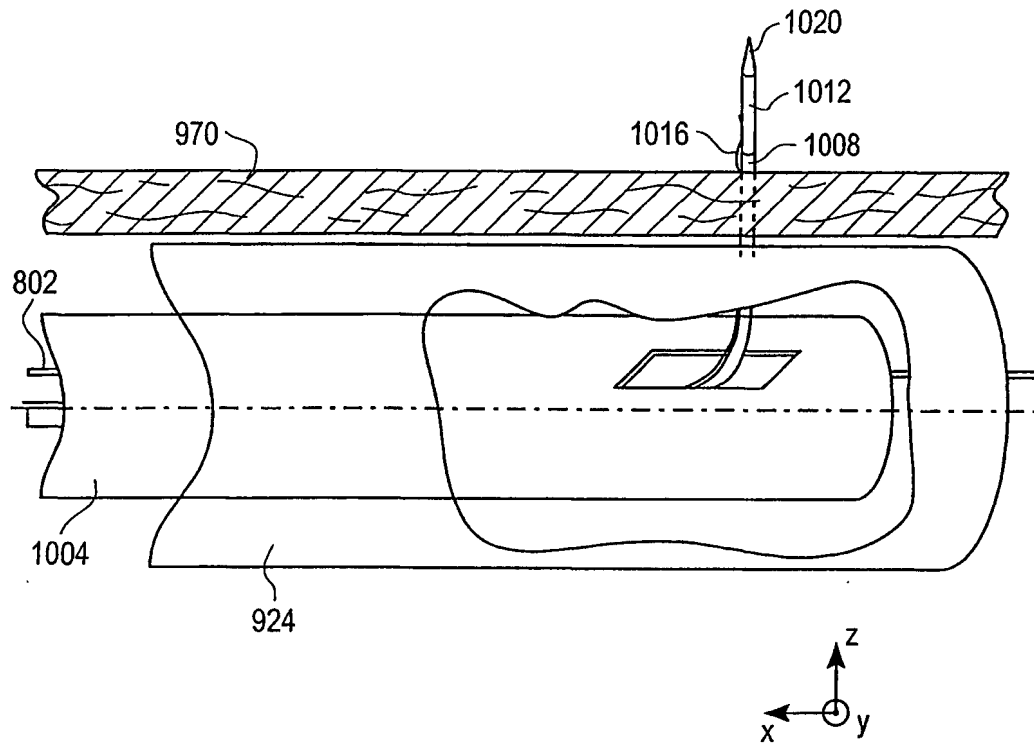
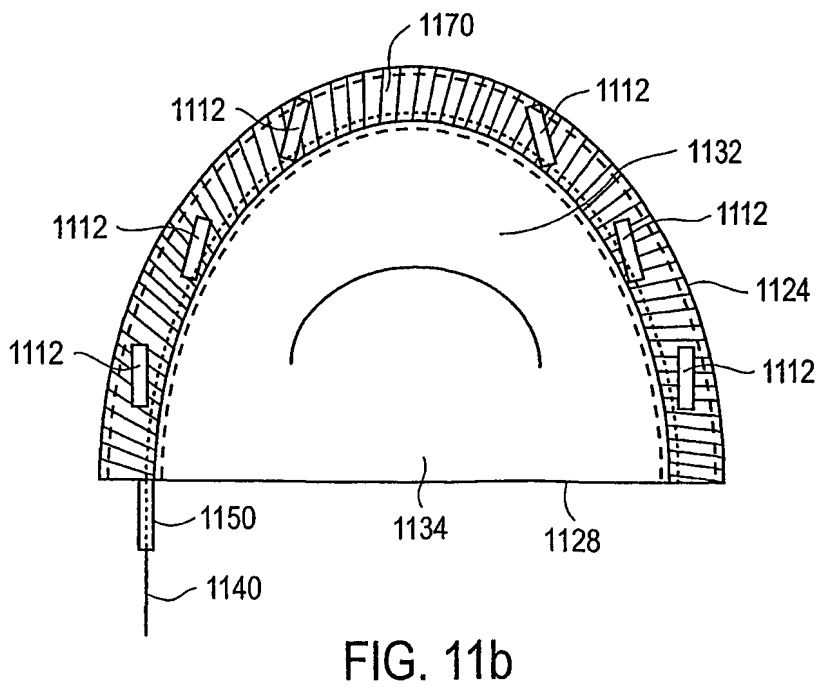
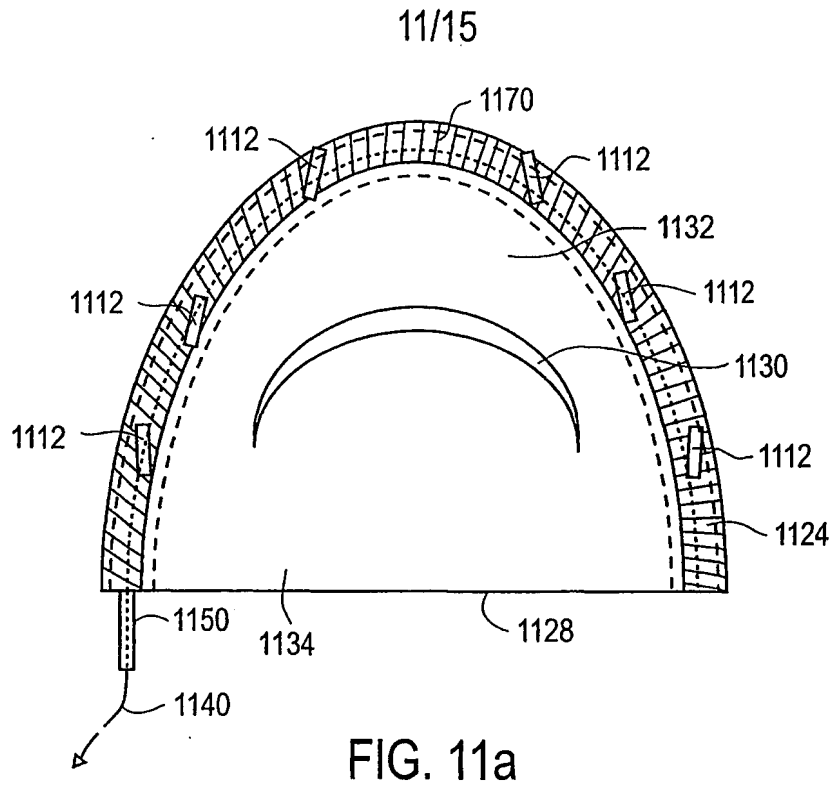


FIG. 10



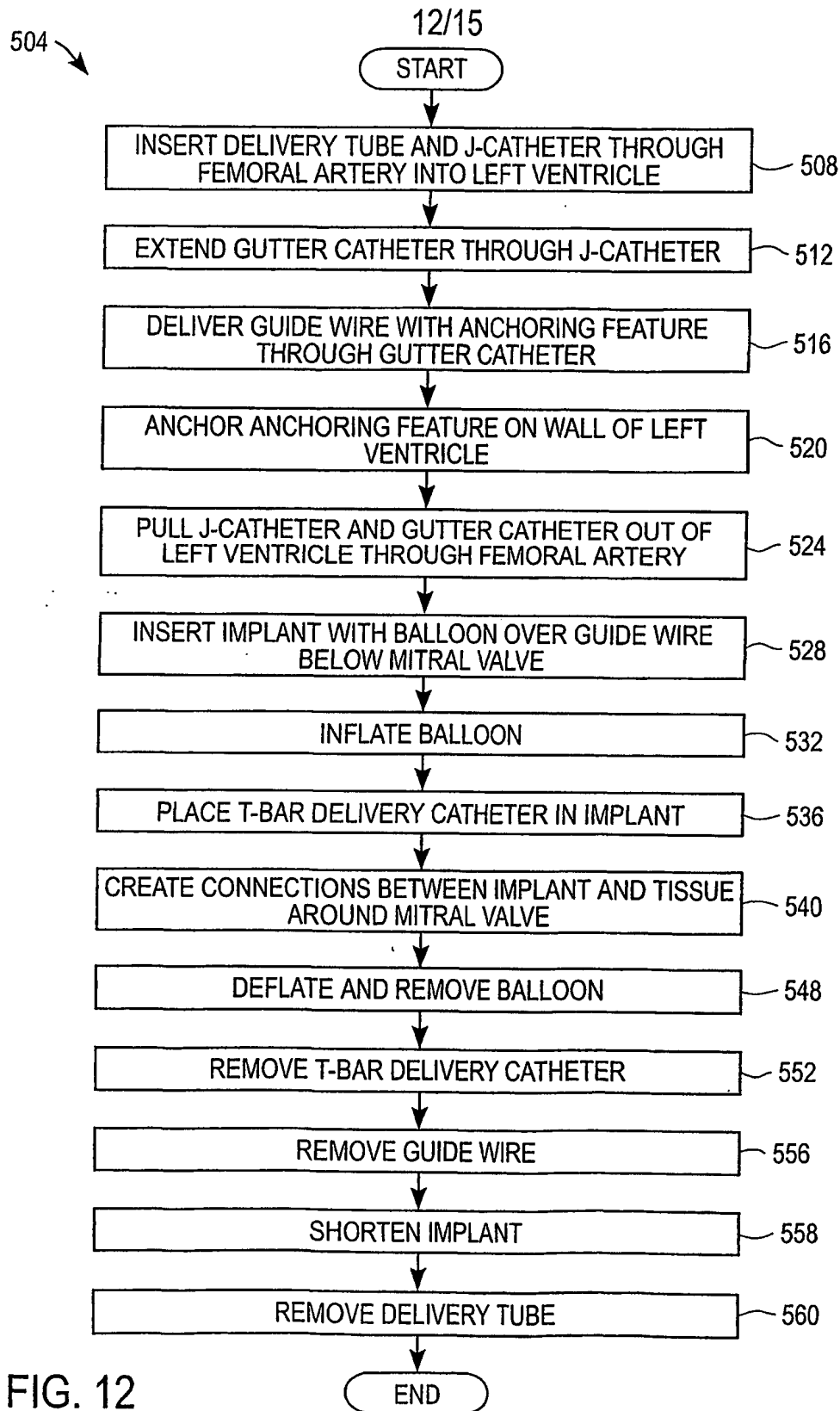


FIG. 12

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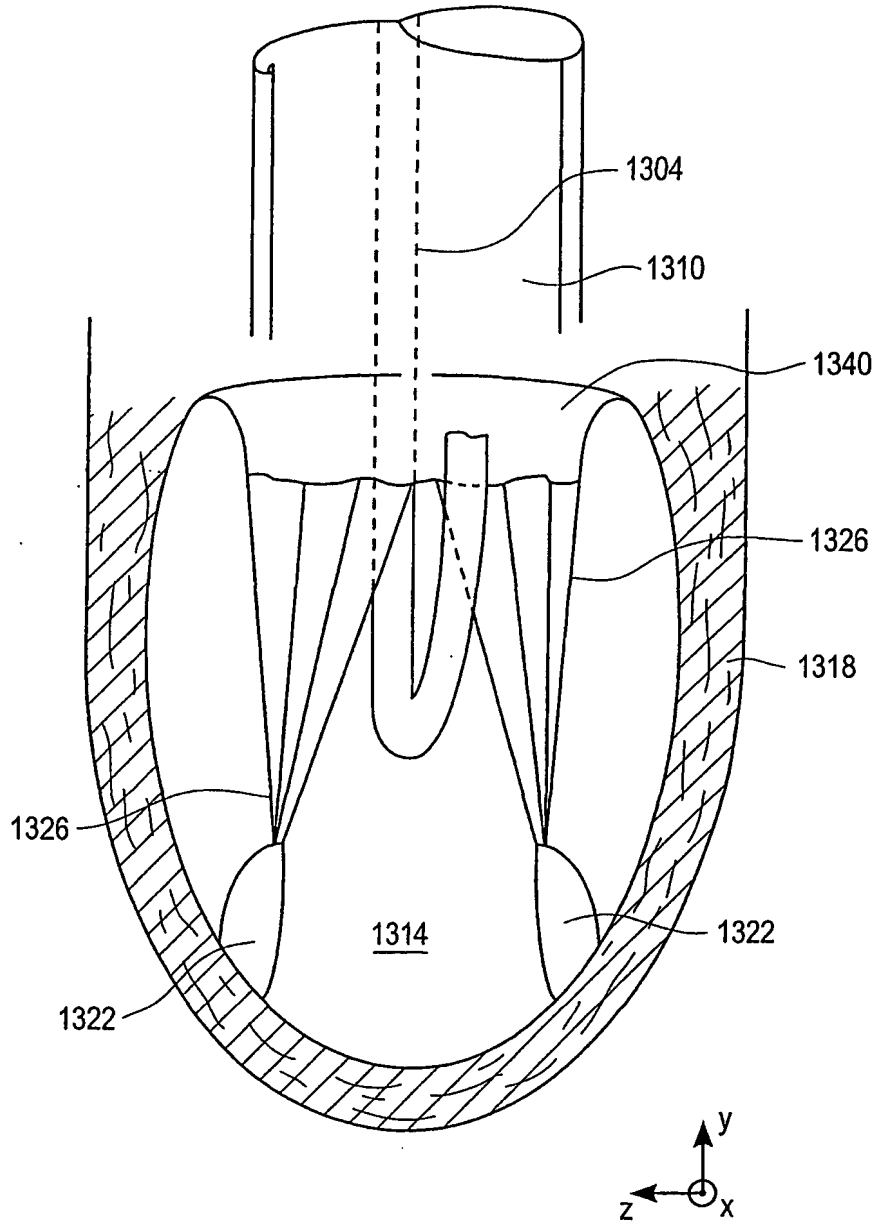


FIG. 13a



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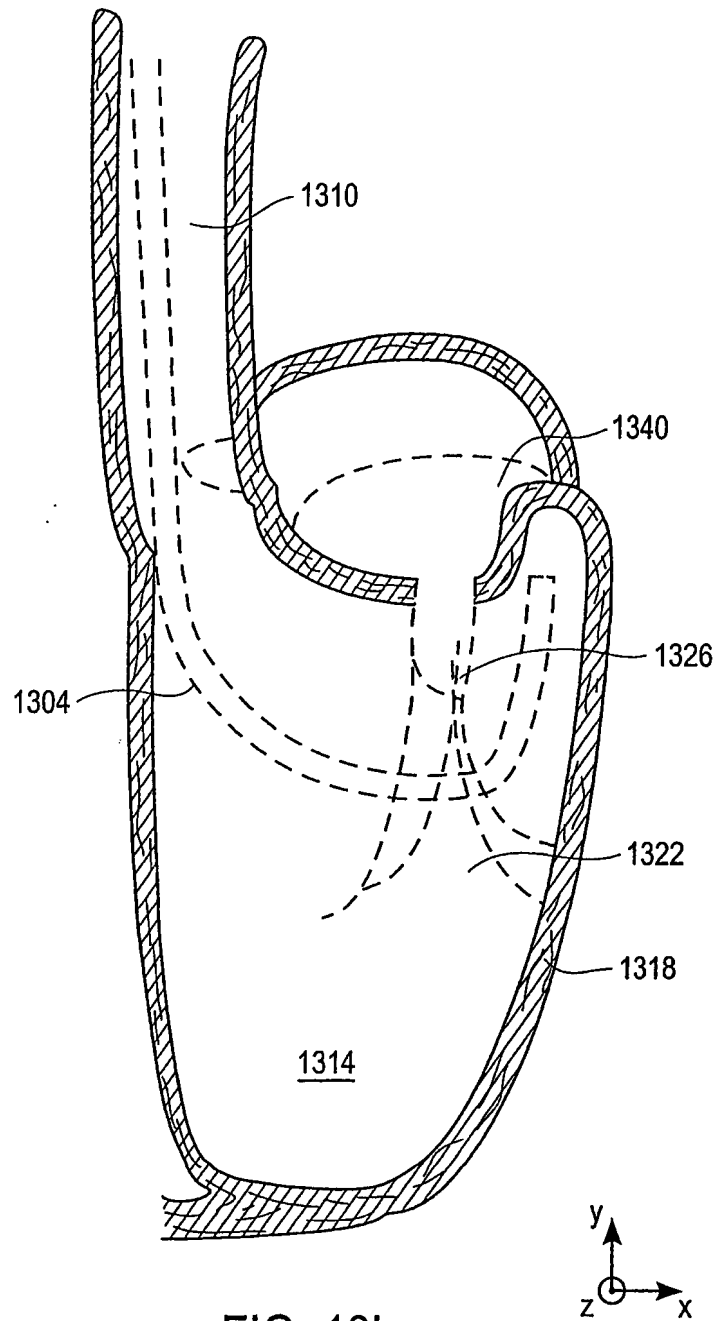


FIG. 13b

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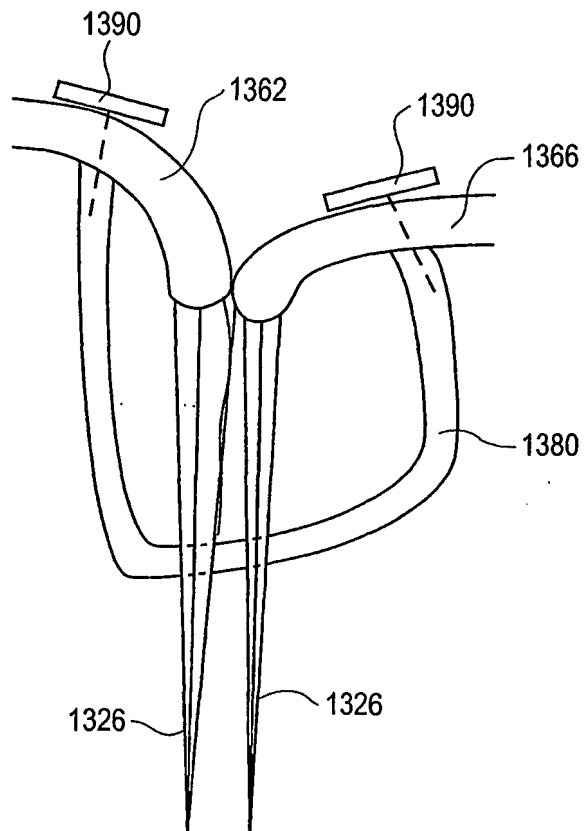
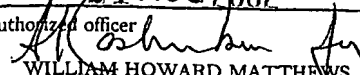


FIG. 13c

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/10952

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(7) : A61F 2/06 US CL : 623/2.37 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) U.S. : 623/2.37 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EAST Search terms: heart, valve, annuloplasty, ring		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00/60995 A (DEEM ET AL) 19 OCTOBER 2000 ENTIRE DOCUMENT.	1,3-10,12-15,17-19,21- 33,35-37,48-55,58.
X	US 5,306,296 A (WRIGHT ET AL) 26 APRIL 1994 ENTIRE DOCUMENT.	38-42,44-47
Y		2,11,43
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "Z" document member of the same patent family	
Date of the actual completion of the international search 06 JUNE 2002		Date of mailing of the international search report 21 AUG 2002
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230		Authorized officer  WILLIAM HOWARD MATTHEWS Telephone No. (703) 305-0316

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- (71) Applicant: VIACOR, INCORPORATED [US/US]; 66 H Concord Street, Wilmington, MA 01887 (US).
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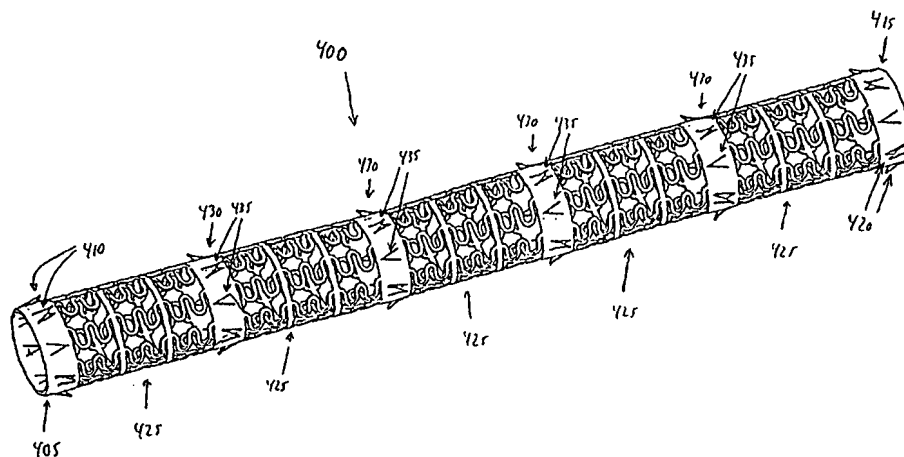
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(74) Agent: PANDISCIO, Mark, J.; Pandiscio & Pandiscio, 470 Totten Pond Road, Waltham, MA 02451-1914 (US).

(54) Title: APPARATUS AND METHOD FOR REDUCING MITRAL REGURGITATION



(57) Abstract: Apparatus for reducing mitral regurgitation, by applying a force to the wall of the coronary sinus so as to force the posterior leaflet anteriorly and thereby reduce mitral regurgitation.

WO 02/096275 A2

APPARATUS AND METHOD FOR REDUCING MITRAL REGURGITATIONReference To Related Application

This patent application claims benefit of pending  
5 prior U.S. Provisional Patent Application Serial  
No. 60/273,893, filed 03/05/01 by William E.  
Cohn et al. for TRANSVASCULAR METHODS AND DEVICES FOR  
MITRAL VALVE PROCEDURES, which application is  
incorporated by reference herein.

Background Of The Invention

Mitral valve repair is the procedure of choice to  
correct mitral regurgitation of all etiologies. With  
the use of current surgical techniques, between 70% and  
15 95% of regurgitate mitral valves can be repaired. The  
advantages of mitral valve repair over mitral valve  
replacement are well documented. These include better  
preservation of cardiac function and reduced risk of  
anticoagulant-related hemorrhage, thromboembolism and  
20 endocarditis.

In current practice, mitral valve surgery requires  
an extremely invasive approach that includes a chest  
wall incision, cardiopulmonary bypass, cardiac and

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pulmonary arrest, and an incision on the heart itself to gain access to the mitral valve. Such a procedure is associated with high morbidity and mortality. Due to the risk associated with this procedure, many of the sickest patients are denied the potential benefits of surgical correction of mitral regurgitation. In addition, patients with moderate, symptomatic mitral regurgitation are denied early intervention and undergo surgical correction only after the development of cardiac dysfunction.

Mitral regurgitation is a common occurrence in patients with heart failure and a source of important morbidity and mortality in these patients. Mitral regurgitation in patients with heart failure is caused by changes in the geometric configurations of the left ventricle, papillary muscles and mitral annulus. These geometric alterations result in mitral leaflet tethering and incomplete coaptation at systole. In this situation, mitral regurgitation is corrected by plicating the mitral valve annulus, either by (i) sutures alone or by (ii) sutures in combination with a support ring, so as to reduce the circumference of the

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distended annulus and restore the original geometry of the mitral valve annulus.

More particularly, current surgical practice for mitral valve repair generally requires that the  
5 posterior mitral valve annulus be reduced in radius by surgically opening the left atrium and then fixing sutures, or more commonly sutures in combination with a support ring, to the internal surface of the annulus; this structure is used to cinch the annulus, in a  
10 pursestring-like fashion, to a smaller radius, thereby reducing mitral regurgitation by improving leaflet coaptation.

This method of mitral valve repair, generally termed "annuloplasty", effectively reduces mitral  
15 regurgitation in heart failure patients. This, in turn, reduces symptoms of heart failure, improves quality of life and increases longevity.

Unfortunately, however, the invasive nature of mitral valve surgery and the attendant risks render most heart  
20 failure patients poor surgical candidates. Thus, a less invasive means to increase leaflet coaptation and thereby reduce mitral regurgitation in heart failure

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patients would make this therapy available to a much greater percentage of patients.

Mitral regurgitation also occurs in approximately 20% of patients suffering acute myocardial infarction.

5 In addition, mitral regurgitation is the primary cause of cardiogenic shock in approximately 10% of patients who develop severe hemodynamic instability in the setting of acute myocardial infarction. Patients with mitral regurgitation and cardiogenic shock have about a  
10 50% hospital mortality. Elimination of mitral regurgitation in these patients would be of significant benefit. Unfortunately, however, patients with acute mitral regurgitation complicating acute myocardial infarction are particularly high-risk surgical  
15 candidates, and are therefore not good candidates for a traditional annuloplasty procedure. Thus, a minimally invasive means to effect a temporary reduction or elimination of mitral regurgitation in these critically ill patients would afford them the time to recover from  
20 the myocardial infarction or other acute life-threatening events and make them better candidates for medical, interventional or surgical therapy.



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Summary Of The Invention

As a result, one object of the present invention is to provide an apparatus and method for treating mitral regurgitation which does not suffer from the disadvantages associated with conventional annuloplasty.

Another object of the present invention is to provide an apparatus and method for treating mitral regurgitation which can be deployed either permanently (e.g., for patients suffering from heart failure) or temporarily (e.g., for patients suffering from mitral regurgitation with acute myocardial infarction).

These and other objects are addressed by the present invention, which is made possible by the discovery that the mitral annulus may be remodeled without the plication of conventional, open-surgery annuloplasty.

With the above and other objects in view, a feature of the invention is the provision of an apparatus for reducing mitral regurgitation. The apparatus comprises:

a bendable elongated body adapted to be inserted into the coronary sinus of a patient in the vicinity of

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the posterior leaflet of the mitral valve, the elongated body being adjustable between a first configuration adapted to be delivered into the coronary sinus and a second configuration adapted to exert a force onto the posterior annulus, the body comprising:

a distal end section having a plurality of proximally-extending barbs;

a proximal end section having a plurality of distally-extending barbs; and

at least one spring segment connecting said distal end section to said proximal end section, said at least one spring segment being adapted to apply a force to said distal end section and said proximal end section so as to urge said distal end section and said proximal end section together;

whereby when said elongated body is inserted into the coronary sinus in the first configuration, said at least one spring segment will cause said elongated body to assume the second configuration so as to exert the force on the posterior annulus and thereby reduce mitral regurgitation.

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In accordance with a further feature of the invention, there is provided a further apparatus for reducing mitral regurgitation. The apparatus comprises:

5           a variable elongated body adapted to be inserted into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the variable elongated body being adjustable between a first configuration adapted to be delivered into the coronary  
10           sinus and a second configuration adapted to exert a force onto the posterior annulus, the variable elongated body comprising:

          a first anchor comprising a first elongated section and a first anchor element disposed at one end  
15           thereof;

          a second anchor having a second elongated section and a second anchor element disposed at one end thereof;

          a crimp having an opening therein and being  
20           adapted to selectively close down the size of the opening;

          said first anchor, said second anchor and said crimp being arranged so that said first elongated

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section and said second elongated section extend through said opening, with said first anchor element and said second anchor element being displaced from one another;

5           whereby said elongated body may be positioned in said first configuration wherein first anchor element and said second anchor element are displaced from one another by a first distance, said elongated body may be deployed in said coronary sinus, and said elongated  
10   body may thereafter be moved into said second configuration wherein said first anchor and said second anchor are displaced from one another by a second, shorter distance, whereby to exert the force on the posterior annulus and thereby reduce mitral  
15   regurgitation.

In accordance with a further feature of the invention, there is provided a method for reducing mitral regurgitation. The method comprises the steps of:

20           providing a prosthesis comprising:

a bendable elongated body adapted to be inserted into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the

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elongated body being adjustable between a first configuration adapted to be delivered into the coronary sinus and a second configuration adapted to exert a force onto the posterior annulus, the body comprising:

5           a distal end section having a plurality of proximally-extending barbs;

          a proximal end section having a plurality of distally-extending barbs; and

          at least one spring segment connecting said distal end section to said proximal end section, said at least one spring segment being adapted to apply a force to said distal end section and said proximal end section so as to urge said distal end section and said proximal end section together;

15           whereby when said elongated body is inserted into the coronary sinus in the first configuration, said at least one spring segment will cause said elongated body to assume the second configuration so as to exert the force on the posterior annulus and thereby reduce mitral regurgitation;

20           positioning the prosthesis in the coronary sinus while in the first configuration; and

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reconfiguring the prosthesis into the second configuration.

In accordance with a further feature of the invention, there is provided a further method for  
5 reducing mitral regurgitation, the method comprising the steps of:

providing a prosthesis comprising:

a variable elongated body adapted to be inserted  
into the coronary sinus of a patient in the vicinity of  
10 the posterior leaflet of the mitral valve, the variable elongated body being adjustable between a first configuration adapted to be delivered into the coronary sinus and a second configuration adapted to exert a  
force onto the posterior annulus, the variable  
15 elongated body comprising:

a first anchor comprising a first elongated section and a first anchor element disposed at one end thereof;

a second anchor having a second elongated section  
20 and a second anchor element disposed at one end thereof;

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a crimp having an opening therein and being adapted to selectively close down the size of the opening;

5       said first anchor, said second anchor and said crimp being arranged so that said first elongated section and said second elongated section extend through said opening, with said first anchor element and said second anchor element being displaced from one another;

10       whereby said elongated body may be positioned in said first configuration wherein first anchor element and said second anchor element are displaced from one another by a first distance, said elongated body may be deployed in said coronary sinus, and said elongated  
15       body may thereafter be moved into said second configuration wherein said first anchor and said second anchor are displaced from one another by a second, shorter distance, whereby to exert the force on the posterior annulus and thereby reduce mitral  
20       regurgitation;

positioning the prosthesis in the coronary sinus while in the first configuration; and

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reconfiguring the prosthesis into the second configuration.

5 The above and other features of the invention, including various novel details of construction and combinations of parts and method steps, will now be more particularly described with reference to the accompanying drawings and pointed out in the claims. It will be understood that the particular devices and methods embodying the invention are shown by way of  
10 illustration only and not as limitations of the invention. The principles and features of this invention may be employed in various and numerous embodiments without departing from the scope of the invention.

15

#### Brief Description Of The Drawings

The above and other objects and features of the present invention are more fully disclosed by the following detailed description of the preferred  
20 embodiments of the invention, which is to be considered together with the accompanying drawings wherein like numbers refer to like parts and further wherein:



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Fig. 1 is a schematic view of portions of the human vascular system;

Fig. 2 is a schematic view of portions of the human heart;

5           Fig. 3 is a side elevational, partly sectional view of a preferred apparatus formed in accordance with the present invention and shown in a first configuration;

10           Figs. 4 is a sectional view taken along line IV-IV of Fig. 3;

Fig. 5 is a side elevational view of the apparatus of Fig. 3 shown in a second configuration;

Fig. 6 is a diagrammatic illustration of an alternative embodiment in a first configuration;

15           Fig. 7 is a diagrammatic illustration of the embodiment of Fig. 6 in a second configuration;

Fig. 8 is a diagrammatic illustration of another alternative embodiment;

20           Fig. 9 is similar to Fig. 8, but illustrative of the embodiment of Fig. 8 in a second configuration;

Fig. 10 is a schematic view of portions of the human heart and illustrating diagrammatically another alternative embodiment of the invention;

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Fig. 11 is a diagrammatic illustration of another alternative embodiment of the present invention;

Fig. 12 is a diagrammatic illustration of still another alternative embodiment of the present invention, with the embodiment being shown in a first configuration and a second configuration;

Figs. 13 and 14 show the embodiment of Fig. 12 applied to the anatomy of a patient, with Fig. 13 showing the embodiment in the aforementioned first configuration and Fig. 14 showing the embodiment in the aforementioned second configuration; and

Figs. 15A-15E are a series of diagrammatic illustrations showing deployment of the embodiment of Figs. 12-14.

#### Detailed Description Of The Preferred Embodiments

The coronary sinus is the largest vein in the human heart. During a large portion of its course in the atrioventricular groove, the coronary sinus typically extends adjacent to the left atrium of the heart for a distance of approximately 5 to 10 centimeters. Significantly, for a portion of its length, e.g., typically approximately 7-9 cm, the

- 15 -

coronary sinus extends substantially adjacent to the posterior perimeter of the mitral annulus. The present invention takes advantage of this fact. More particularly, by deploying an elongated body in the coronary sinus, adjacent to the posterior leaflet of the mitral valve, pressure may be brought to bear on the posterior annulus of the mitral valve, whereby to move the posterior annulus anteriorly so as to improve leaflet coaptation and, as a result, reduce mitral regurgitation. In this respect it should be appreciated that the posterior annulus may be shifted anteriorly so as to achieve, or to attempt to achieve to the extent anatomically possible, leaflet-to-leaflet engagement or leaflet-to-annulus engagement (e.g., where a leaflet may be tethered due to left ventricular distortion). Both of these types of engagement, or targeted engagement, are intended to be encompassed by the terms "improved leaflet coaptation" and/or "increased leaflet coaptation" and the like.

In one preferred embodiment of the invention, access to the coronary sinus is gained percutaneously, e.g., the elongated body is introduced into the

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patient's vascular system via the jugular vein or via the left subclavian vein, passed down the superior vena cava, passed through the right atrium and then passed into the coronary sinus, where it is deployed.

5 Alternatively, the elongated body may be introduced into the coronary sinus through a small incision in the heart, or through some other incision into the patient's vascular system.

10 Once deployed, the elongated body may be left in position permanently (e.g., in the case of patients suffering from mitral regurgitation associated with heart failure) or the elongated body may be left in position only temporarily (e.g., in the case of patients suffering from mitral regurgitation associated with acute myocardial infarction).

15 Visualization of the procedure may be obtained by fluoroscopy, echocardiography, intravascular ultrasound, angiography, real-time magnetic resonance imaging, etc. The efficacy of the procedure may be determined through echocardiography, although other  
20 imaging modalities may also be suitable.

Looking now at Fig. 1, there are shown aspects of the cardiovascular system 3 of a patient. More

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particularly, cardiovascular system 3 generally comprises the heart 6, the superior vena cava 9, the right subclavian vein 12, the left subclavian vein 15, the jugular vein 18, and the inferior vena cava 21.

5 Superior vena cava 9 and inferior vena cava 21 communicate with the heart's right atrium 24. The coronary ostium 27 leads to coronary sinus 30. At the far end 31 (Fig. 2) of coronary sinus 30, the vascular structure turns into the vertically-descending antero-

10 interventricular vein ("AIV") 32 (see Fig. 1). For purposes of the present invention, it can generally be convenient to consider the term "coronary sinus" to mean the vascular structure extending between coronary ostium 27 and AIV 32.

15 As seen in Fig. 2, between coronary ostium 27 and AIV 32, coronary sinus 30 generally extends substantially adjacent to the posterior perimeter of the annulus 33 of the mitral valve 36. Mitral valve 3 comprises a posterior leaflet 39 and an anterior

20 leaflet 42. In the case of a regurgitant mitral valve posterior leaflet 39 and anterior leaflet 42 will generally fail to properly coapt at systole, thereby

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leaving an intervening gap 45 which will permit regurgitation.

Referring to Fig. 3, it will be seen that an illustrative preferred embodiment includes an elongated flexible body 50. The body 50 preferably is provided with a rounded or pointed distal end 52 for insertion into the coronary sinus 30 (Fig. 5).

Fixed to the distal end 52 of the body 50 is a wire 54 which extends through the body 50, with a proximal portion P thereof extending proximally from body 50 (Fig. 3). The body 50 is provided with wire supporting portions 58, each of which defines a channel 60 (Fig. 4) for retaining the wire 54, but permitting the wire 54 to slide therethrough. Wire 54 is preferably positioned on one side of the longitudinal axis of body 50, and body 50 preferably includes a plurality of openings 55 helping to define a plurality of flexible bridges 56.

The body 50 may be provided with barbs 62 for engagement with tissue in the coronary sinus 30. When barbs 62 are used, the elongated body 50 should be housed in a guide catheter 64 (Fig. 4) which is removed once the body 50 is in place, to expose barbs 62.

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As body 50 is inserted into coronary sinus 30, it will generally assume the shape of the coronary sinus, which is naturally curved in the region of the posterior leaflet of the mitral valve. Thereafter, wire 54 may be pushed or pulled, as desired, so as to alter the configuration of body 50. More specifically, by pushing the wire 54 in a distal direction, the body 50 is caused to reconfigure to a tighter arc around the mitral valve annulus 33, i.e., by bending on bridges 56 and enlarging openings 55. By pulling the wire 54 proximally, the body is caused to reconfigure to a more extended arc, or to assume a straight configuration, or even to assume an inverted configuration, by bending on bridges 56 and reducing openings 55. Either alteration of the configuration of body 50 in turn alters the configuration of the coronary sinus adjacent to the mitral valve, whereby to force the posterior annulus anteriorly and thereby improve leaflet coaptation and hence reduce mitral regurgitation.

Looking next at Fig. 6, there is shown an alternative embodiment of the present invention. More particularly, there is shown an elongated body 100 which comprises a plurality of staples 103 connected by

- 20 -

a flexible bridge 105. A wire 110 has one end secured to the distalmost end of bridge 105. During use, the elongated body 100 is positioned within the coronary sinus (Fig. 7), staples 103 are secured to the walls of the coronary sinus 30, and then wire 110 is pushed distally or pulled proximally so as to modify the configuration of elongated body 100. More particularly, pulling wire 110 proximally will cause bridge 105 to reconfigure to a tighter arc around the mitral valve annulus, whereas pushing wire 110 distally will cause bridge 105 to reconfigure into a more extended arc, or to go straight, or even to invert. This action in turn alters the configuration of the coronary sinus 30 adjacent to the mitral valve 36, whereby to force the posterior annulus anteriorly and thereby improve leaflet coaptation and hence reduce mitral regurgitation.

Looking next at Fig. 8, there is shown another alternative embodiment of the present invention. More particularly, there is shown an elongated body 200 which comprises a plurality of anchors 205, formed by staples, or the like, each comprising an eyelet through which extends a wire 210. The distal end of wire 210



- 21 -

is secured to the distalmost staple. During use, the elongated body 200 is positioned within the coronary sinus, the anchors 205 are secured to the walls of the coronary sinus 30, and then wire 210 is pulled

5 proximally so as to modify the configuration of elongated body 200. More specifically, pulling of the wire 210 causes the body 200 to reconfigure to a wider arc (Fig. 9) and then, if pulled further, to a substantially straight configuration. Such action, in

10 turn, alters the configuration of the coronary sinus 30 adjacent to the mitral valve 36, whereby to force the posterior annulus anteriorly and thereby improve leaflet coaptation and hence reduce mitral regurgitation.

15 Looking next at Fig. 10, there is shown another embodiment of the present invention. More particularly, there is shown an elongated body 300 which is adapted to reducing mitral regurgitation by scarring the mitral valve annulus 33 to cause

20 contraction thereof. Elongated body 300 includes an element at its distal end which is adapted to inject a scarring medium into the mitral valve annulus. This scarring medium may comprise a chemical, or it may

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comprise energy selected from a group of energies consisting of thermal, cryogenic, laser and radio frequency.

Looking next at Fig. 11, there is shown an  
5 elongated body 400 which comprises a self-cinching version of the invention. More particularly, body 400 comprises a distal end section 405 including a plurality of proximally-extending barbs 410, a proximal  
10 end section 415 including a plurality of distally-extending barbs 420, and one or more spring segments 425 connecting distal end section 405 to proximal end section 415. If desired, intermediate sections 430, with or without associated barbs 435, may be disposed between spring segments 425.

15 In use, elongated body 400 is positioned in coronary sinus 30 with its one or more spring sections 405 configured in an extended condition, and then the one or more spring sections 425 are reconfigured into a contracted condition so that the device's distal end  
20 section 405 and proximal end section 415 are drawn together. This action will cause barbs 410 and 420 to set into the surrounding tissue and draw this tissue closer together. With elongated body 400 residing in

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coronary sinus 30 and drawing separated sections of the curved coronary sinus closer together, the coronary sinus is effectively straightened and the posterior leaflet 39 is forced anteriorly, whereby to reduce or completely eliminate mitral regurgitation.

If desired, the one or more spring sections 425 may be formed out of a resilient material, e.g., a resilient metal or plastic. In this case, the one or more spring sections 425 may be restrained in an extended condition when the elongated body 400 is positioned in the coronary tissue; and the one or more spring sections 425 may thereafter be released so as to draw together distal end section 405 and proximal end section 415. Alternatively, the one or more spring sections 425 may be formed out of a so-called shape memory alloy, with a temperature transition being used to effect the desired shortening of the one or more spring sections 425 when the coronary sinus is to be straightened.

Looking next at Fig. 12, there is shown a device 500 which is intended to minimize trauma to the coronary sinus wall by fixating at only two points and then cinching between those two points, using the

- 24 -

coronary sinus as a guide path for the cinching mechanism. To this end, device 500 comprises an anterolateral anchor 505 having a hook 510 and a posteromedial anchor 515 having a hook 520. Hooks 510 and 520 are shown in Fig. 12 as simple curved shapes with sharp tips, however, other configurations may also be used, e.g., barbs or staples or suture knots. A ratcheting mechanism is preferably used to effect cinching between anchors 505 and 515. In one preferred embodiment of the present invention, the ratcheting mechanism is bi-directional and is achieved by creating a rough or saw-toothed surface 525 on anchor 505 and a rough or saw-toothed surface 530 on anchor 515. Fixation crimp 535 forces the two surfaces 525 and 530 together so as to keep them from slipping relative to one another. In one form of the invention, fixation crimp 535 is an elastomeric material of sufficient durometer to allow the two anchors to be forced apart when desired but which will normally not move under the loads associated with cardiac function. Alternatively, crimp 535 may be formed of a deformable material that is crimped

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after the two anchors 505 and 510 have been cinched together.

5 In use, device 500 is deployed in the coronary sinus 30 with its anchors 505 and 515 in an extended configuration; hooks 510 and 520 are set into the wall of the coronary sinus; and then anchors 505 and 515 are ratched together so as to bring hocks 510 and 520 (and hence remote portions of tissue) together, whereby to straighten the coronary sinus and thereby  
10 reduce mitral regurgitation. Fig. 13 shows the device 500 in an initial, uncinched configuration, and Fig. 14 shows the device 500 in a final, cinched configuration, with the resulting plication of mitral annulus 33.

15 Figs. 15A-15E show one embodiment of device 500 being deployed and cinched. Device 500 is introduced into the coronary sinus via an outer sheath 540. Hooks 510 and 520 are made of a resilient material such as Nitinol, stainless steel or plastic, and are  
20 stretched flat by the outer sheath 540. A push rod 545 and pull rod 550 form a cinching device 555. In this embodiment, push rod 545 is temporarily connected to device 500 by a threaded hole in crimp

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535. Pull rod is temporarily connected to device 500 by a threaded hole in the proximal end of anterolateral anchor 505. When push rod 545 and pull rod 550 are moved in relationship to each other, the device 500 changes length by a distance 560 shown in Fig. 12.

Fig. 15B shows anchor 505 emerging from outer sheath 540 and regaining its original curved shape. This can be effected by pushing the device 500 distally with push rod 545. As anchor 505 emerges from outer sheath 540, its hook 510 will engage in the adjacent tissue.

Fig. 15C shows anchor 515 emerging from sheath 540 and regaining its original curved shape. As anchor 515 emerges from outer sheath 540, its hook 520 will engage in the adjacent tissue.

Fig. 15D shows pull rod 550 being moved relative to push rod 545 so as to reduce the overall length of device 500. As this occurs, opposing hooks 510 and 520 will draw the tissue together, so as to plicate mitral annulus 33 and thereby reduce mitral regurgitation.

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Fig. 15E shows cinching device 555 removed from annuloplasty device 500 by unscrewing both pull rod 555 and push rod 545.

5 It is to be understood that the present invention is by no means limited to the particular constructions and method steps herein disclosed and/or shown in the drawings, but also comprises any modifications or equivalents within the scope of the claims.

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What Is Claimed Is:

1. Apparatus for reducing mitral regurgitation,  
the apparatus comprising:

5 a bendable elongated body adapted to be inserted  
into the coronary sinus of a patient in the vicinity of  
the posterior leaflet of the mitral valve, the  
elongated body being adjustable between a first  
configuration adapted to be delivered into the coronary  
10 sinus and a second configuration adapted to exert a  
force onto the posterior annulus, the body comprising:

a distal end section having a plurality of  
proximally-extending barbs;

15 a proximal end section having a plurality of  
distally-extending barbs; and

at least one spring segment connecting said distal  
end section to said proximal end section, said at least  
one spring segment being adapted to apply a force to  
said distal end section and said proximal end section  
20 so as to urge said distal end section and said proximal  
end section together;

whereby when said elongated body is inserted into  
the coronary sinus in the first configuration, said at



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least one spring segment will cause said elongated body to assume the second configuration so as to exert the force on the posterior annulus and thereby reduce mitral regurgitation.

5

2. Apparatus according to claim 1 wherein the at least one spring segment comprises an elastic material, and further wherein said elastic material is stretched when said elongated body is in the first configuration and said elastic material is relaxed when said elongated body is in the second configuration.

10

3. Apparatus according to claim 1 wherein said at least one spring segment comprises a shape memory alloy, and further wherein a temperature transition is used to transform said elongated body from the first configuration to the second configuration.

15

4. Apparatus according to claim 1 wherein there are at least two spring segments connecting said distal end section to said proximal end section, and further wherein an intermediate section is disposed between said at least two spring segments.

20

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5. Apparatus according to claim 4 wherein said intermediate section has at least one barb thereon.

5           6. Apparatus for reducing mitral regurgitation, the apparatus comprising:

          a variable elongated body adapted to be inserted into the coronary sinus of a patient in the vicinity of the posterior leaflet of the mitral valve, the variable  
10 elongated body being adjustable between a first configuration adapted to be delivered into the coronary sinus and a second configuration adapted to exert a force onto the posterior annulus, the variable elongated body comprising:

15           a first anchor comprising a first elongated section and a first anchor element disposed at one end thereof;

          a second anchor having a second elongated section and a second anchor element disposed at one end  
20 thereof;

          a crimp having an opening therein and being adapted to selectively close down the size of the opening;

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said first anchor, said second anchor and said crimp being arranged so that said first elongated section and said second elongated section extend through said opening, with said first anchor element and said second anchor element being displaced from one another;

whereby said elongated body may be positioned in said first configuration wherein first anchor element and said second anchor element are displaced from one another by a first distance, said elongated body may be deployed in said coronary sinus, and said elongated body may thereafter be moved into said second configuration wherein said first anchor and said second anchor are displaced from one another by a second, shorter distance, whereby to exert the force on the posterior annulus and thereby reduce mitral regurgitation.

7. Apparatus according to claim 6 wherein said first anchor element comprises a first hook at one end of said first elongated section.

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8. Apparatus according to claim 6 wherein said second anchor element comprises a second hook at one end of said first elongated section.

5 9. Apparatus according to claim 6 wherein said crimp is made of elastic material.

10 10. Apparatus according to claim 9 wherein at least one of said anchors comprises a saw-toothed surface for engaging the other of said anchors.

11. Apparatus according to claim 6 wherein said crimp is made of a material which will take a set.

15 12. A method for reducing mitral regurgitation, the method comprising the steps of:  
providing a prosthesis comprising:  
a bendable elongated body adapted to be inserted  
into the coronary sinus of a patient in the vicinity of  
20 the posterior leaflet of the mitral valve, the elongated body being adjustable between a first configuration adapted to be delivered into the coronary

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sinus and a second configuration adapted to exert a force onto the posterior annulus, the body comprising:

a distal end section having a plurality of proximally-extending barbs;

5 a proximal end section having a plurality of distally-extending barbs; and

at least one spring segment connecting said distal end section to said proximal end section, said at least one spring segment being adapted to apply a force to  
10 said distal end section and said proximal end section so as to urge said distal end section and said proximal end section together;

whereby when said elongated body is inserted into the coronary sinus in the first configuration, said at  
15 least one spring segment will cause said elongated body to assume the second configuration so as to exert the force on the posterior annulus and thereby reduce mitral regurgitation;

positioning the prosthesis in the coronary sinus while in the first configuration; and  
20

reconfiguring the prosthesis into the second configuration.

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13. A method for reducing mitral regurgitation,  
the method comprising the steps of:

providing a prosthesis comprising:

5           a variable elongated body adapted to be inserted  
into the coronary sinus of a patient in the vicinity of  
the posterior leaflet of the mitral valve, the variable  
elongated body being adjustable between a first  
configuration adapted to be delivered into the coronary  
10          sinus and a second configuration adapted to exert a  
force onto the posterior annulus, the variable  
elongated body comprising:

          a first anchor comprising a first elongated  
section and a first anchor element disposed at one end  
15          thereof;

          a second anchor having a second elongated section  
and a second anchor element disposed at one end  
thereof;

          a crimp having an opening therein and being  
20          adapted to selectively close down the size of the  
opening;

          said first anchor, said second anchor and said  
crimp being arranged so that said first elongated

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section and said second elongated section extend through said opening, with said first anchor element and said second anchor element being displaced from one another;

5           whereby said elongated body may be positioned in said first configuration wherein first anchor element and said second anchor element are displaced from one another by a first distance, said elongated body may be deployed in said coronary sinus, and said elongated  
10   body may thereafter be moved into said second configuration wherein said first anchor and said second anchor are displaced from one another by a second, shorter distance, whereby to exert the force on the posterior annulus and thereby reduce mitral  
15   regurgitation;

          positioning the prosthesis in the coronary sinus while in the first configuration; and

          reconfiguring the prosthesis into the second configuration.

20

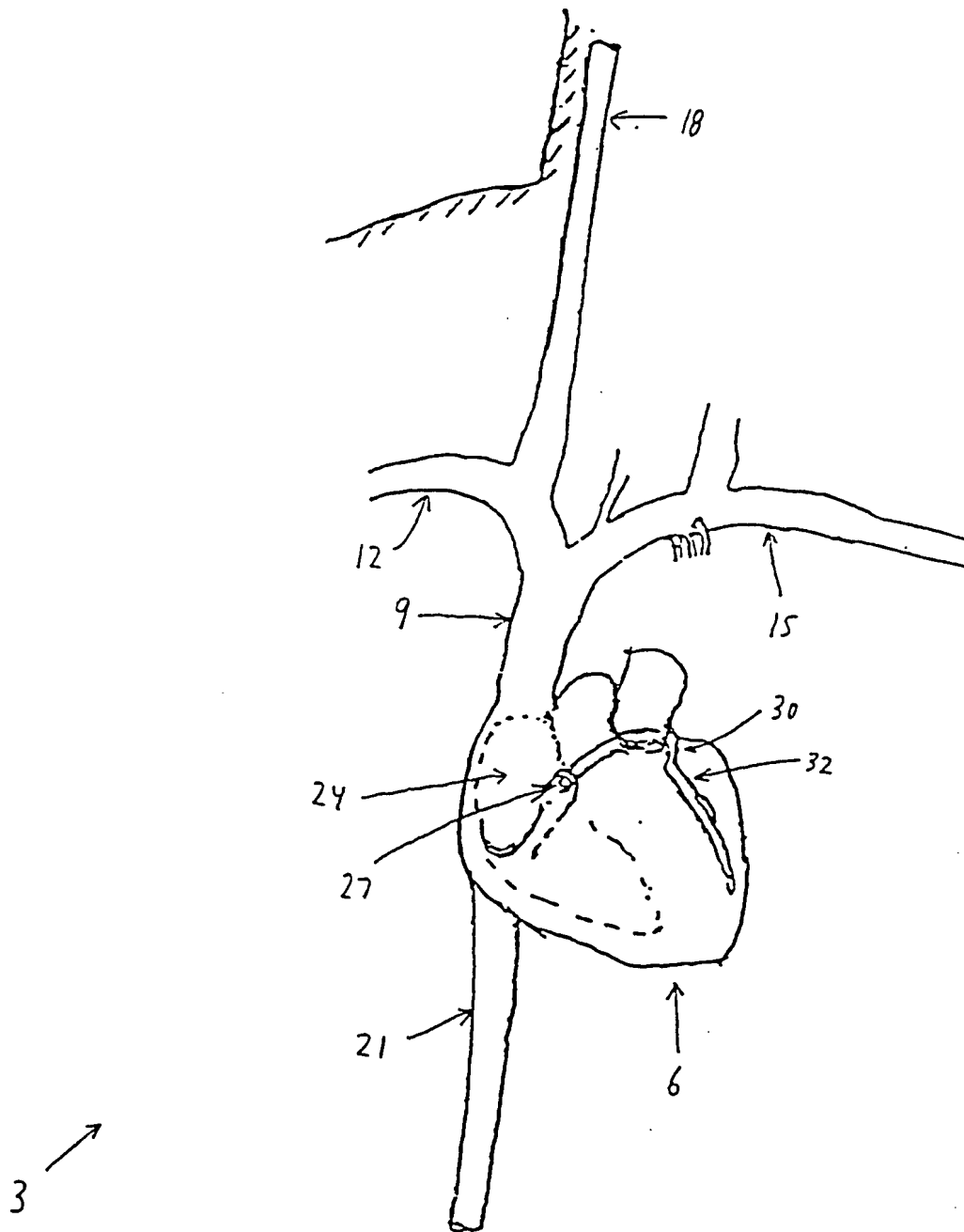


FIG. 1



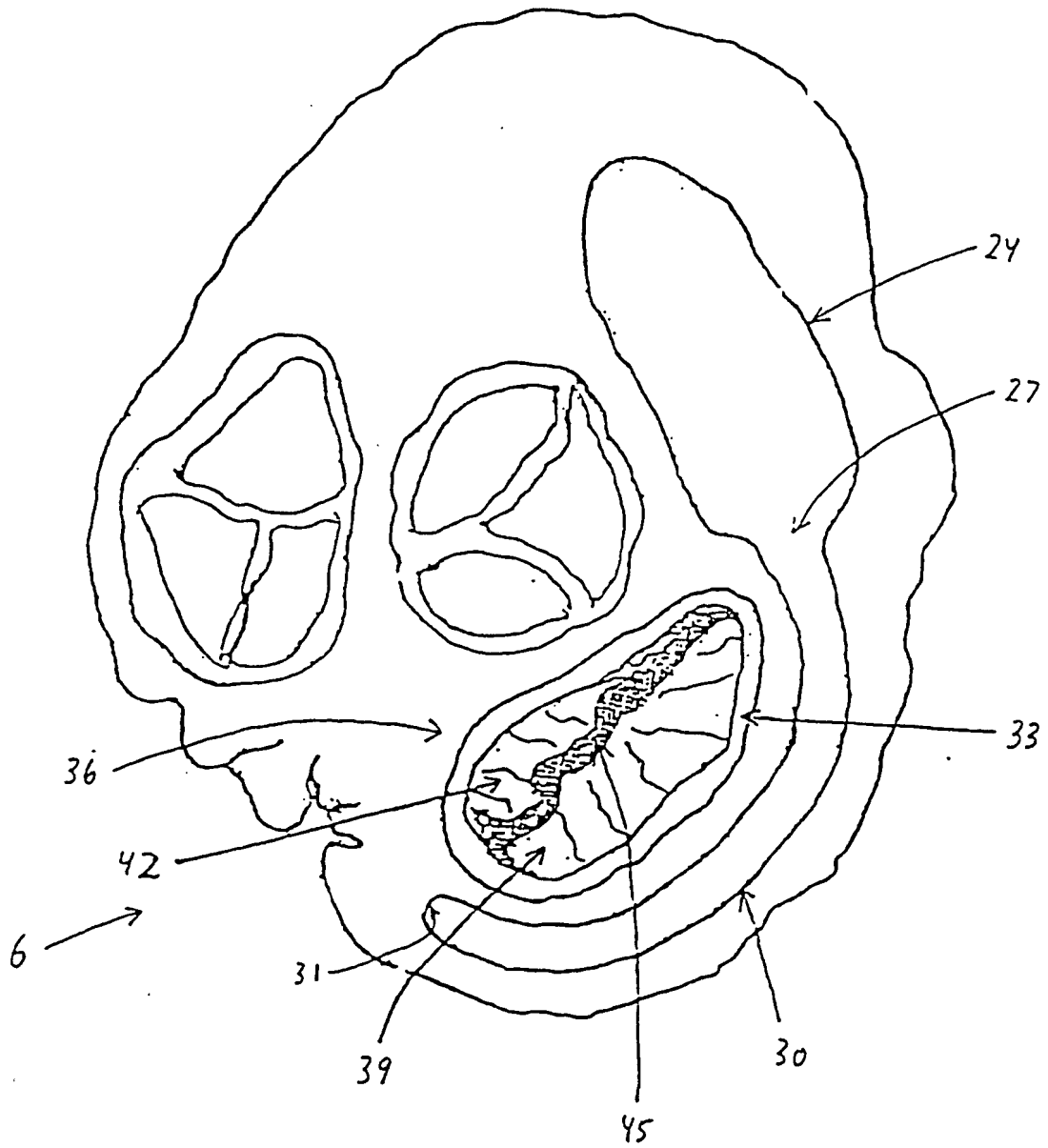
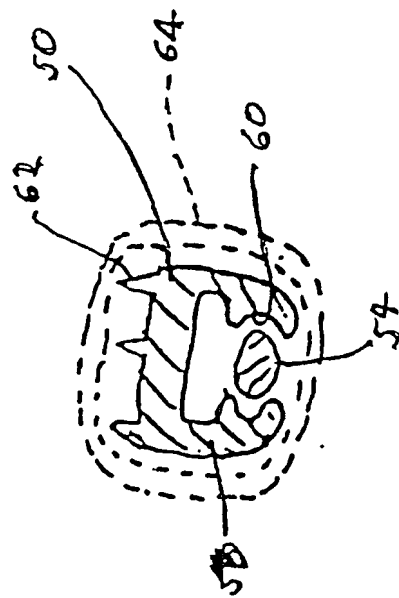
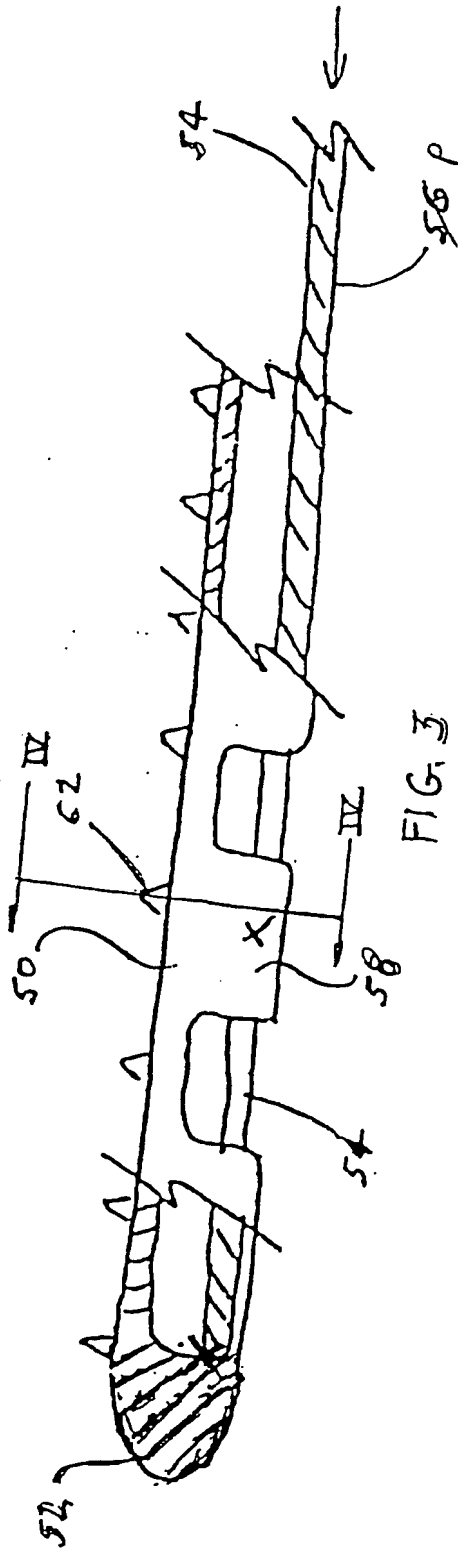


FIG. 2



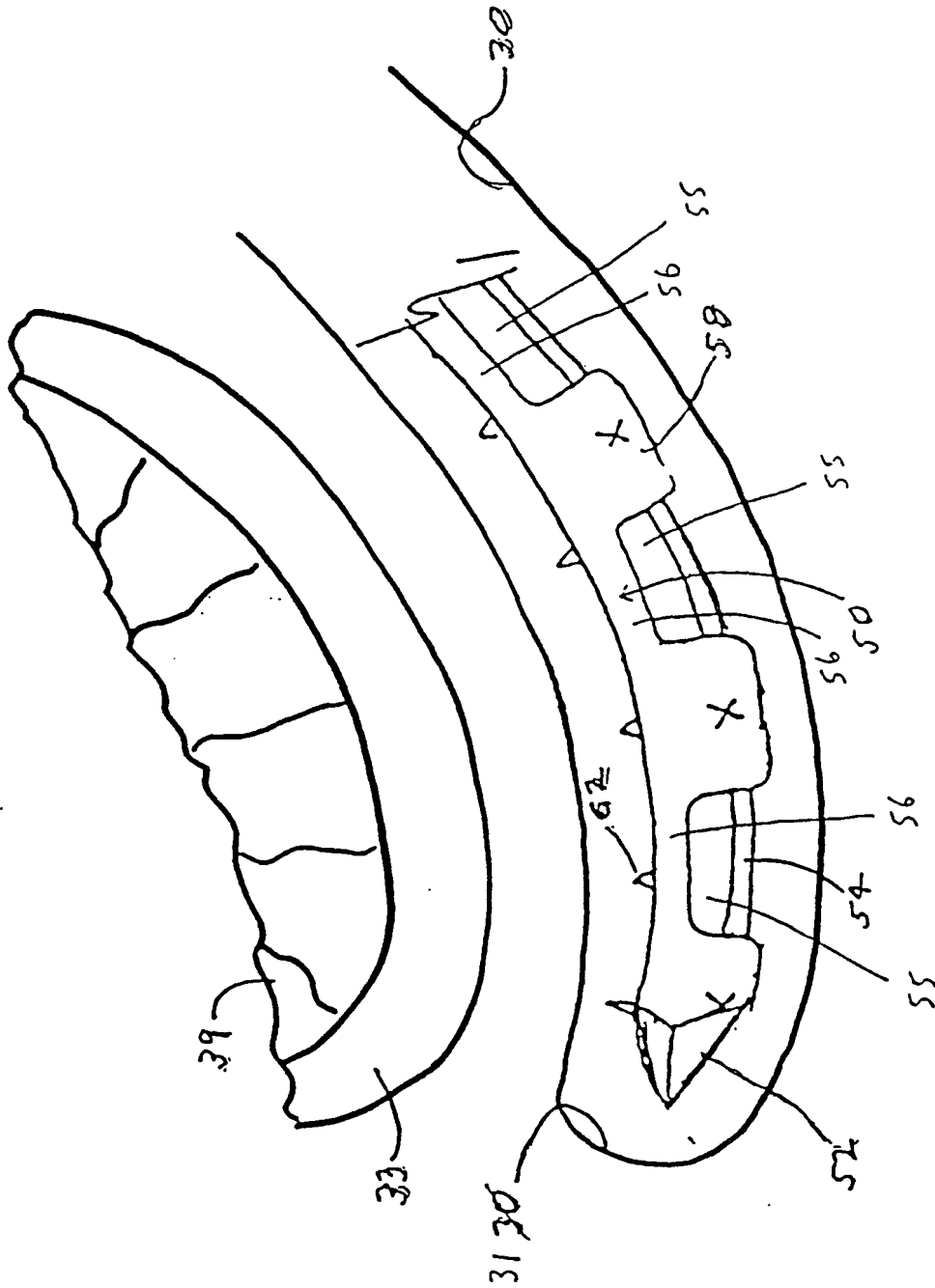
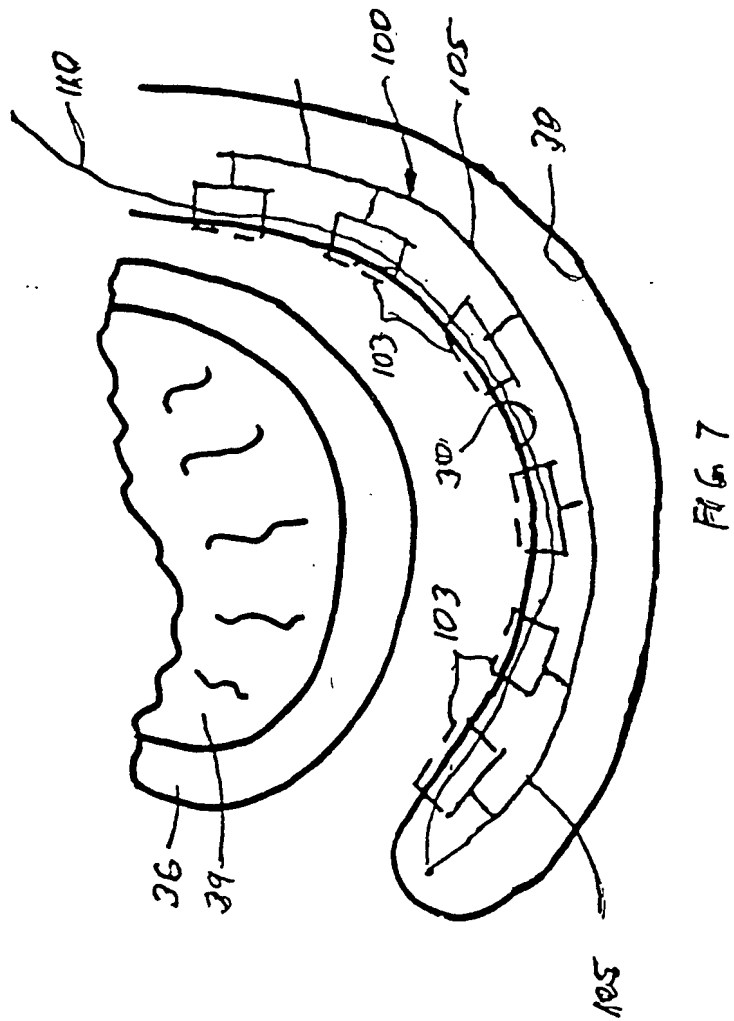
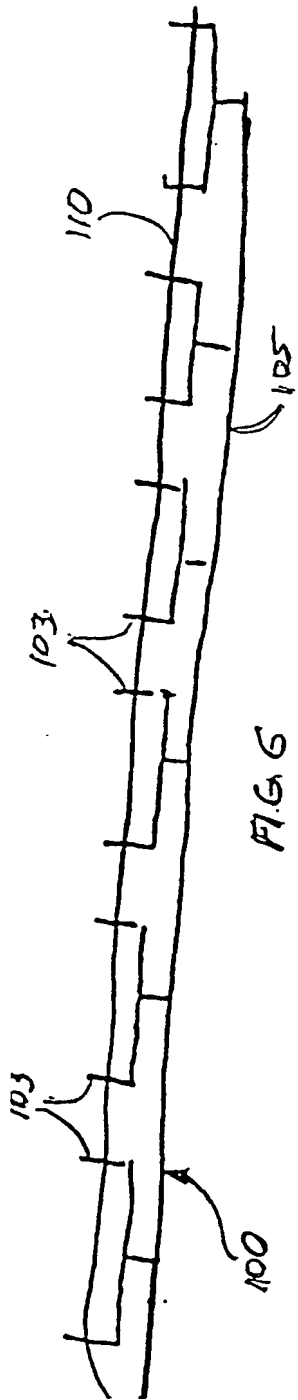


FIG. 5



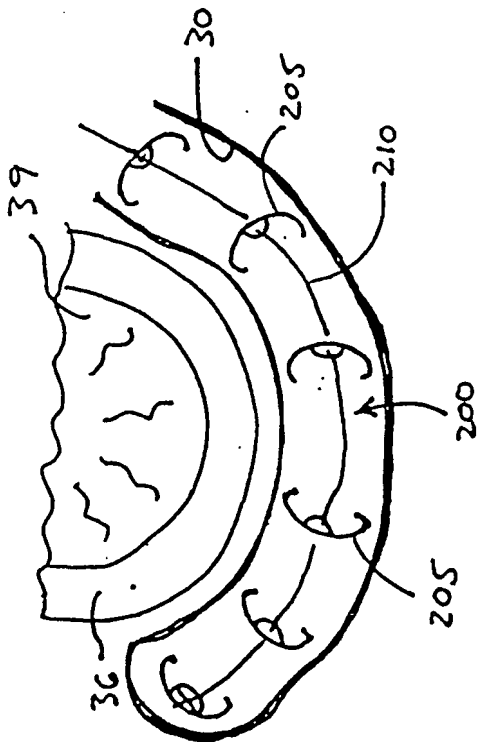


Fig 8

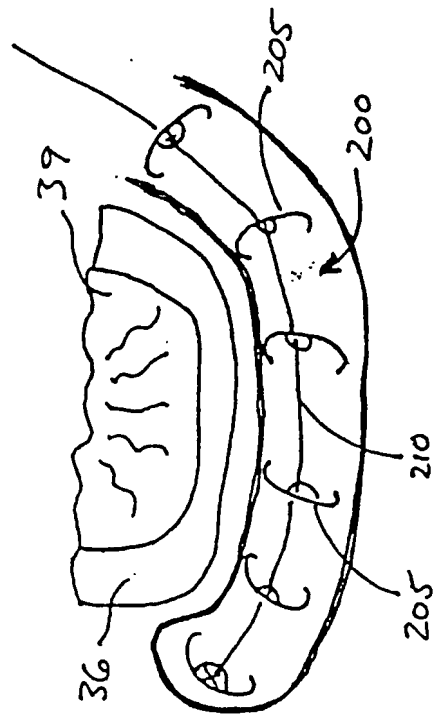


Fig 9

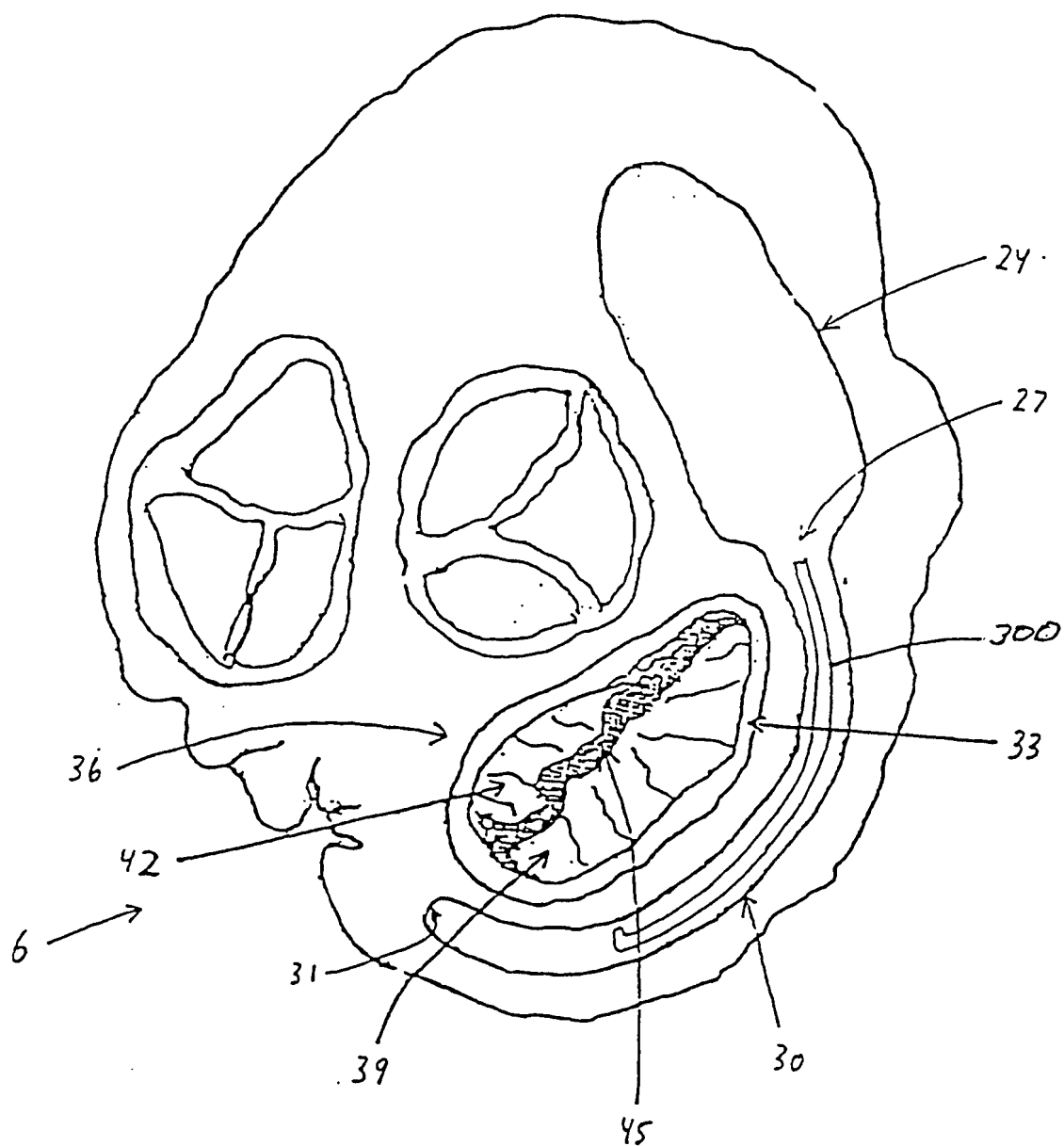


FIG. 10

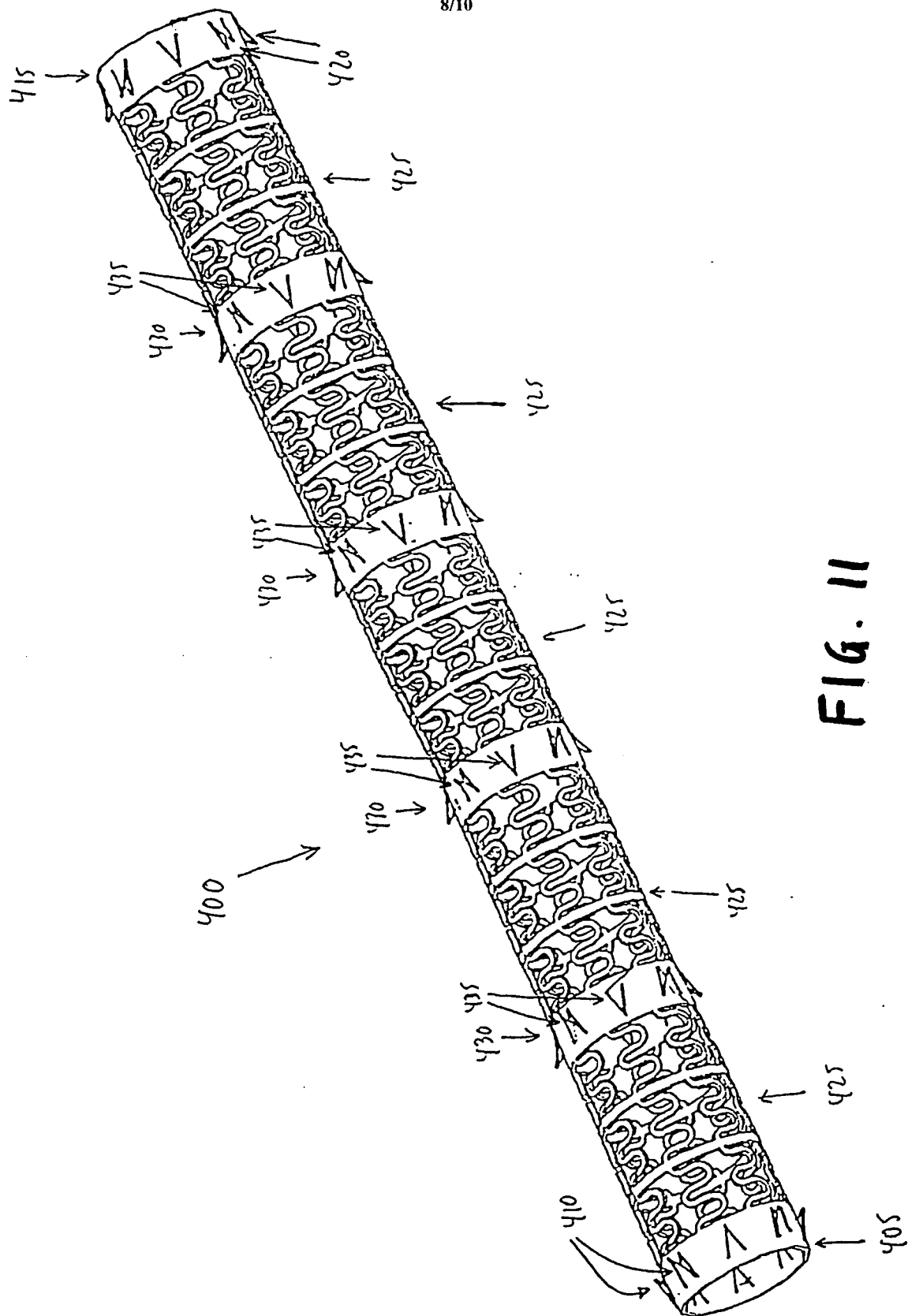


Fig. 11

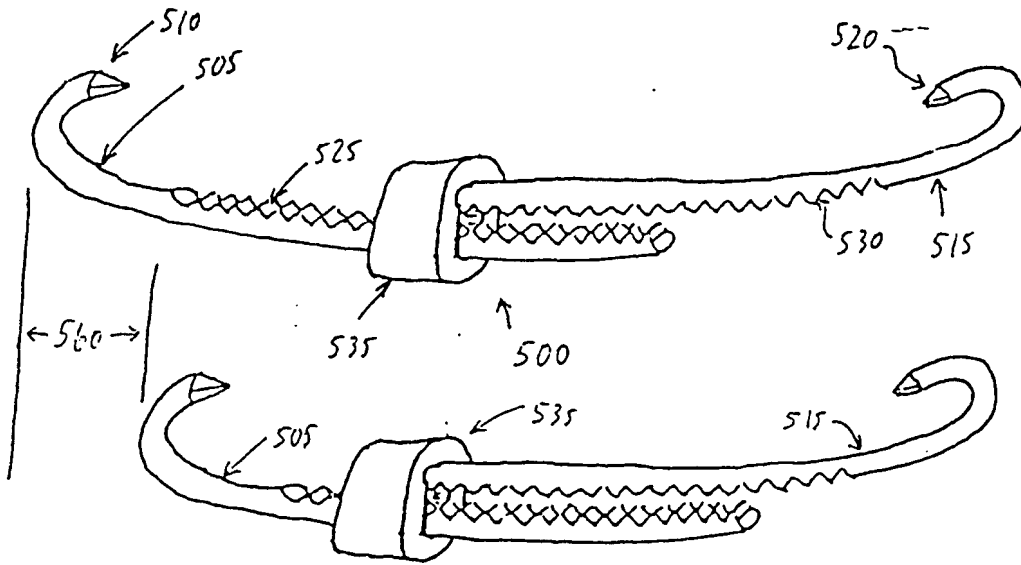


FIG. 12

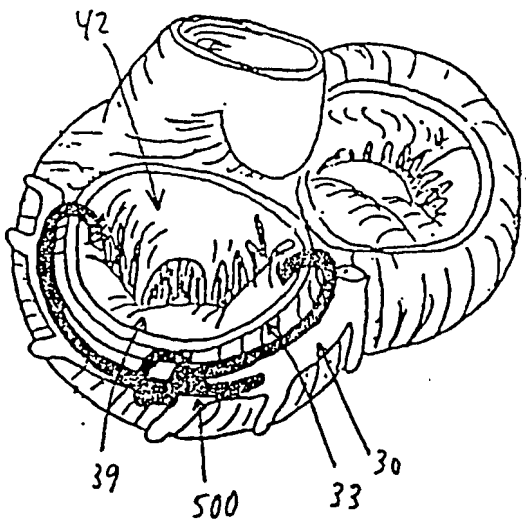


FIG. 13

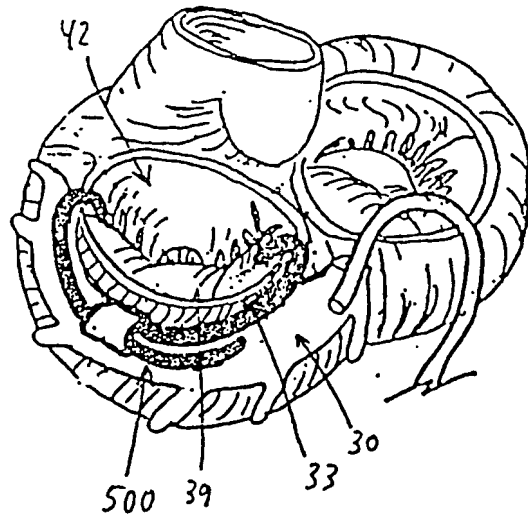


FIG. 14



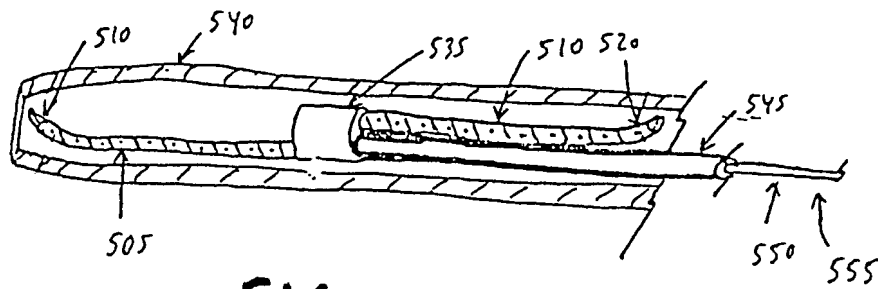


FIG. 15A

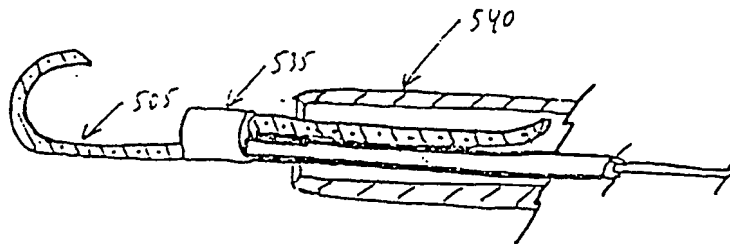


FIG. 15B

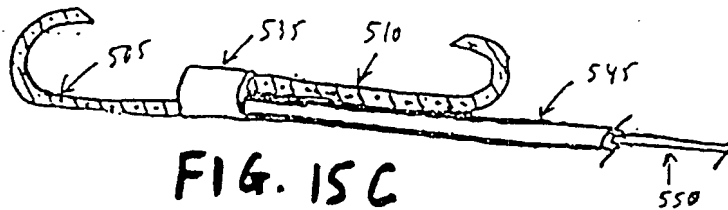


FIG. 15C

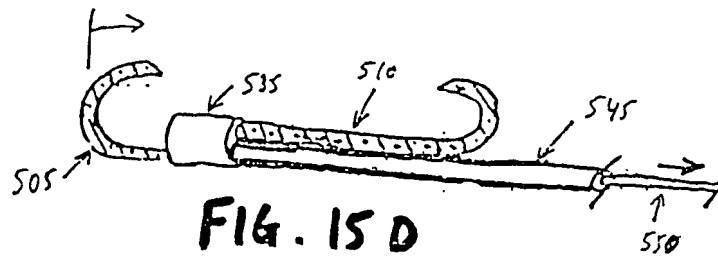


FIG. 15D

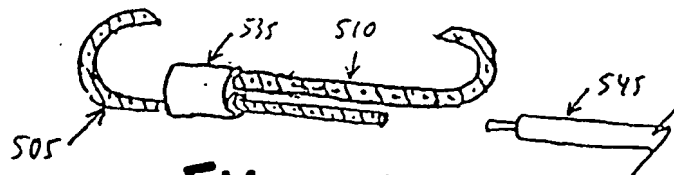


FIG. 15E



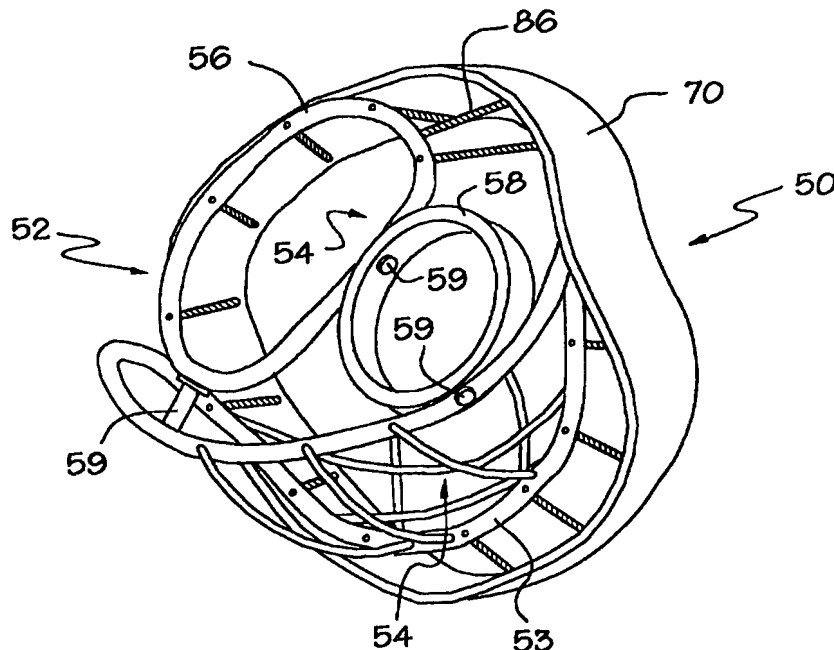
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: <b>PCT/US97/00374</b></p> <p>(22) International Filing Date: <b>2 January 1997 (02.01.97)</b></p> <p>(30) Priority Data: <b>08/581,914</b>      <b>2 January 1996 (02.01.96)</b>      <b>US</b></p> <p>(71)(72) Applicant and Inventor: <b>MELVIN, David, Boyd</b> [US/US]; University of Cincinnati, College of Medicine, 231 Bethesda Avenue, Cincinnati, OH 45267-0558 (US).</p> <p>(74) Agents: <b>ROTMAN, Phillip, A., II et al.; Dinsmore &amp; Shohl</b> L.L.P., 1900 Chemed Center, 255 East Fifth Street, Cincinnati, OH 45202 (US).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b> <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: ACTIVATION DEVICE FOR THE NATURAL HEART AND METHOD OF DOING THE SAME

## (57) Abstract

An activator device for activation of cardiac tissue having a stint for placement within the interior volume of a natural heart adjacent cardiac tissue thereof. The device also includes a yoke for placement around a portion of the exterior surface of the natural heart in general alignment with the stint and connected to the stint by at least one cord. The device provides a simple yet reliable mechanism for assisting in extended activation of a natural heart with minimal impact and intrusion.



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**ACTIVATION DEVICE FOR THE NATURAL HEART  
AND METHOD OF DOING THE SAME**

David Boyd Melvin, M.D.

**TECHNICAL FIELD OF THE INVENTION**

The present invention relates to a device and method for assisting in the activation and operation of a living heart, and more specifically, for mechanically deforming cardiac tissue such that the circulation of blood is maintained.

**BACKGROUND OF THE INVENTION**

5           The natural heart, and specifically, the cardiac tissue of the natural heart can fail for various reasons to a point where the natural heart cannot provide sufficient circulation of blood for a body so that life can be maintained. As a solution for the failing natural heart, several attempts have been made in the past to provide a device to maintain circulation.

10           One such approach has been to either assist or to entirely replace the existing natural heart in a patient with an artificial heart, or to transplant a natural heart from another human into a patient. Several drawbacks have limited use of prior devices to applications having far too brief of a time period to provide a real lasting benefit, and to transplant use in a tiny fraction of those afflicted with heart disease or malfunction.

15           A particular problem stems from the fact that the materials used for the interior lining of the chambers of an artificial heart are in direct contact with the circulating blood, which can enhance undesirable clotting of the blood, build up of calcium, or otherwise inhibit the blood's normal function. Hence, thromboembolism and hemolysis

could occur with greater ease. Additionally, an artificial heart lining can crack, which inhibits performance, even if the crack is at a microscopic level.

5 The transplant procedure requires removing an existing organ (i.e., the natural heart) for substitution with another organ (i.e., another natural heart) from another human, or potentially, from an animal. Before replacing an existing organ with another, the substitute organ must be "matched" to the recipient, which can be, at best, difficult and time consuming to accomplish. Furthermore, even if the transplanted organ matches the recipient, a risk exists that the recipient's body will reject the transplanted organ and attack it as a foreign object. Moreover, the number of potential donor hearts is far less  
10 than the number of patients in need of a transplant. Although use of animal hearts would lessen the problem with fewer donors than recipients, there is an enhanced concern with rejection of the animal heart.

In an effort to use the existing natural heart of a patient, other attempts have been made to wrap skeletal muscle tissue around the natural heart to use as an auxiliary  
15 contraction mechanism to pump the natural heart. As currently used, skeletal muscle cannot alone typically provide sufficient and sustained pumping power for maintaining circulation of blood through the circulatory system of the body, especially for those patients with severe heart failure.

20 Still another concept for maintaining the existing natural heart as the pumping device involves enveloping a substantial portion of the natural heart, such as the entire left and right ventricles, with a pumping device for rhythmic compression. Although somewhat effective as a short term treatment, the pumping device has not been suitable

for long term use. Typically, a vacuum pressure is needed to overcome cardiac tissue/wall stiffness so that the chambers can return to their original volume and refill with blood. This "active filling" of the chambers with blood limits the ability of the pumping device to respond to the need for adjustments in the blood volume pumped through the natural heart, and can adversely affect the circulation of blood to the coronary arteries. Natural heart valves are quite sensitive to wall and annular distortion, and movement patterns that reduce a chamber's volume do not necessarily facilitate valve closure (which can lead to valve leakage). Another major obstacle with long term use of such pumping devices is the deleterious effect of extensive mechanical contacting of living internal surfaces (endocardium). In certain cases, this coaption of endocardium tissue is probably mechanically necessary for a device that encompasses both ventricles to produce independent output pressures, but it can compromise the integrity of the living endothelium.

Another device developed for use with an existing heart for sustaining the circulatory function of a living being and the pumping action of the natural heart is an external bypass system, such as a cardiopulmonary (heart-lung) machine. Typically, bypass devices of this type are complex and large, and, as such, are limited to short term use in an operating room during surgery, or to maintaining the circulation of a patient while awaiting receipt of a transplant heart. The size and complexity effectively prohibit use of bypass systems as a long term solution, as they are rarely even portable devices. Furthermore, long term use of a heart lung machine can damage the blood cells and blood

borne products, resulting in post surgical complications such as bleeding, thromboembolism function, and increased risk of infection.

Consequently, none of the previous available techniques or devices for maintaining circulation of blood provided an adequate or practical long-term use device or technique for adequately maintaining sufficient blood pressure and circulation of blood through the circulatory system of the body.

### **SUMMARY OF THE PRESENT INVENTION**

It is the object of the present invention to provide a device and method for activation of a natural heart that provides different independent pressures to the left and right side of the natural heart.

It is another object of the present invention to provide a device and method for activation of a natural heart that minimizes damage to the coronary circulatory and the endocardium (lining tissue).

It is still a further another object of the present invention to provide a device and method for activation of a natural heart that allows one or more of the heart chambers to rapidly and passively refill at low pressure after an activation stroke.

Another object of the present invention is to provide a device and method for the activation of a natural heart that supports and maintains competence of the heart valves so the heart valves can function as designed.

Still another object of the present invention is to provide a device and method for the activation of the heart that functions at the proper rate.

Yet another object of the present invention is to provide an apparatus and method for the activation of a natural heart on a long term basis.

It is yet still an object of the present invention to provide a device and method for the activation of a natural heart to provide an implant device that does not require removal of an existing natural heart.

Additional objects, advantages, and other features of the present invention will be set forth and will become apparent to those skilled in the art upon examination of the following, or may be learned with practice of the invention.

To achieve the foregoing and other objects, and in accordance with the purpose herein, the present invention comprises an activator device for use with a natural heart having an internal stint for placement within the interior volume of a natural heart adjacent cardiac tissue. The device also includes a yoke for placement around a portion of the exterior surface of the natural heart in general alignment with the stint and is connected to the stint by at least one cord.

Preferably, the activator device includes a first ring for placement around at least one of the atrioventricular valve annuli, a second ring for placement around at least one of the outflow valve or semilunar annuli, and a septal splint having a frame and sutures in a net-like configuration to stabilize the septal wall between chambers of the natural heart. The first ring, second ring, and the septal splint are connected to each other using fastening elements.

In a preferred embodiment, the yoke is sized and configured for placement adjacent at least a portion of the interventricular groove, preferably adjacent at least a



portion of the anterior and posterior portions of the interventricular groove, and more preferably adjacent at least a substantial portion of the anterior and posterior portions of the interventricular groove. In another embodiment, the yoke is sized and configured for placement adjacent at least a portion of the atrioventricular groove.

5           The present invention also includes an activator attached to the yoke for deforming the natural heart, which preferably includes a hydraulic lateral arm.

          The present invention also includes a method for cardiac tissue deformation using the above-described device. The activator deforms a portion of the cardiac tissue by moving an arm from a relaxed condition to an activated condition. As the activator is pressing against the natural heart, the volume of at least one chamber of the natural heart is decreased so that blood is pumped out of the natural heart and into the circulatory system. Thereafter, the activator releases from against a portion of the cardiac tissue returns to the relaxed condition. The combination of the stint and yoke assist in returning the volume of the chamber so that at least one of the chambers of the natural heart refills with blood and thus, the steps can be repeated.

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          Different forces can be applied to a natural heart for reducing the volume of at least one of the chambers. These forces can include applying a torsion force or a shearing to the natural heart, flattening a portion of the cardiac tissue, applying a uniform pressure to the natural heart, and/or applying an indentation against at least one point on the exterior wall of the natural heart.

20

**BRIEF DESCRIPTION OF THE DRAWINGS**

While the specification concludes with claims particularly pointing out and distinctly claiming the present invention, it is believed the same will be better understood from the following description taken in conjunction with the accompanied drawings in which:

Fig. 1 is a partial frontal anterior perspective view of an exemplary natural heart;

Fig. 2 is a perspective view of an internal stint and exterior yoke made in accordance with the present invention;

Fig. 3 is a partial cross-sectional view of a natural heart with a septal splint made in accordance with the present invention placed within a natural heart;

Fig. 4 is a partial frontal perspective view of a natural heart with an external yoke placed on a natural heart;

Fig. 5A is a frontal perspective view of one embodiment of the external yoke and activator of the present invention;

Fig. 5B is a frontal perspective view of another embodiment of an external yoke and activator of the present invention;

Fig. 6 is a top sectional schematic view of a natural heart with an internal splint and an external yoke of the present invention illustrated being connected by transmural cords;

Fig. 7A is a partial schematic view of an exemplary activator of the present invention in a relaxed condition; and

Fig. 7B is a partial schematic view of an exemplary activator of the present invention in an activated condition.

### **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT**

Referring now to the figures in detail wherein like numerals indicate the same elements throughout the views, a natural heart, generally indicated in Figure 1 as 10, has a lower portion comprising two chambers, namely a left ventricle 12 and a right ventricle 14, which function primarily to supply the main force that propels blood through the circulatory system. A natural heart 10 also includes an upper portion having two chambers, a left atrium 16 and a right atrium 18, which primarily serve as an entryway to the left and right ventricles 12 and 14, respectively, and assist in moving blood into the left and right ventricles 12 or 14. The interventricular wall of cardiac tissue separating the left and right ventricles 12 and 14, respectively, is defined by an interventricular groove 20 on the exterior wall of the natural heart 10. The anteroventricular wall of cardiac tissue separating the lower ventricular region from the upper atrium region is defined by anteroventricular groove 22 on the exterior wall of the natural heart 10.

Generally, the ventricles are in fluid communication with the atria through an atrioventricular valve. More specifically, the left ventricle 12 is in fluid communication with the left atrium 16 through the mitral valve, while the right ventricle 14 is in fluid communication with the right atrium 18 through the tricuspid valve. Generally, the ventricles are in fluid communication with the circulatory system (i.e., the pulmonary and peripheral circulatory system) through semilunar valves. More specifically, the left

ventricle 12 is in fluid communication with the aorta 26 of the peripheral circulatory system, through the aortic valve, while the right ventricle 14 is in fluid communication with the pulmonary artery 28 of the pulmonary, circulatory system through the pulmonic valve.

5           By way of a non-limiting example, the present invention will be discussed in terms of embodiments that are used to primarily assist in the activation and operation of the left ventricular portion of the natural heart 10, however, it is noted that the present invention can also be used to assist in the activation and operation of other portions of the natural heart 10, such as the atria, or the right ventricular portion of the natural heart 10. The present invention is a mechanical activator, illustrated in Figure 2 as 50, which includes an internal stint 52. Furthermore, the present invention includes an external yoke 70 fixed to the internal stint 52 by transmural cords 86. The internal stint 52 is sized and configured for placement within the interior volume of the natural heart 10, and includes a generally triangular shaped frame 53 that can be assembled from a plurality of interlocking struts, preferably an anterior, a posterior and a basal strut. The stint 52 also includes at least two separate ring structures, namely a first ring 56 sized and configured for placement adjacent the atrioventricular valve annuli, and preferably suprajacent the mitral valve annuli in the left atrium 16, and a second ring 58 sized and configured for placement adjacent the semilunar valve annuli preferably subjacent the aortic valve annuli in the left ventricle 12.

Figure 3 further illustrates a septal splint 54, which can include one or more strands of sutures affixed to the frame 53 through loops positioned on the frame 53,

preferably the loops are affixed to the inner portion of frame 53, and more preferably, at about 1.5 cm intervals. The splint 54 can take the form of a tennis racket-like shaped configuration or a snowshoe like shaped configuration to brace or stabilize one side of the septum, preferably the right side of the interventricular septum without distortion of the chordae. Preferably, the septal splint 54 is positioned by stringing a heavy monofilament polypropylene suture, such as a #5 polypropylene suture, under, through, and behind the trabeculae, and through the loops as will be discussed later in great detail. The first and second rings 56 and 58 and the septal splint 52 are attached at least to each other using a connector element 59, such as a pin to assist in maintaining the relative position so that the first and second rings 56 and 58, respectively, and the splint 52 are supported while the natural heart 10 is being activated.

So that the components of the stint 52 (e.g., the septal splint 54 and first and second rings 56 and 58) are not totally rigid and can exhibit an elastic quality, the components are preferably made of a stiff coil spring material covered with braided polyester. Localized adjustments can be made to the elasticity of the various components of the stint 52 to reduce the potential for problems, such as damaging the cardiac tissue or compromising the coronary circulation.

As illustrated in Figure 4, the device 50 also includes an external yoke 70 for placement around a portion of the exterior surface of a natural heart 10. The generally stirrup shaped yoke 70 restricts free motion of the natural heart 10 so that the natural heart 10 can be activated. Preferably, the yoke 70 can be between about 1 and 2 cm wide and includes a semi-rigid collar portion, preferably made of polypropylene, for providing

rigidity to the yoke 70. Additionally, the yoke 70 can include a gel-filled cushion portion that is positioned immediately adjacent exterior surface of the natural heart 10 for providing equalized pressure over the irregularities in the epicardial surface of the natural heart 10, and preferably, any of the coronary arteries 30 within each region under the yoke 70. Preferably, the yoke 70 is sized and configured for placement adjacent at least a portion of the atrioventricular groove 22, more preferably, at least a portion of the anterior and posterior portions of the interventricular groove 20, and most preferably, at least a substantial portion of the anterior and posterior portion of the interventricular groove. In yet another embodiment, the yoke 70 is sized and configured for placement adjacent at least a portion of the atrioventricular groove 22.

Referring now to Fig. 6, general alignment of the yoke 70 is maintained by at least one transmural cord 86, and preferably, a plurality of cords 86 that penetrate the walls of the natural heart 10 and connect to the stint 52. The cord 86 is preferably made of a heavy braided, polymer-impregnated polyester suture core (such as # 5 Ethiband® by Ethicon, Inc.) covered in the intermyocardial portion with a braided sleeve of polyester yarn to promote firm tissue growth around the cord 86. When it is necessary to utilize more than one cord 86 with the present invention, spacing of the cords 86 should preferably be at intervals of between about 15 mm to 20 mm along the yoke 70, from the septal splint 54 and the first ring 56 extending obliquely outwardly toward the left ventricle exterior wall for insertion into the left ventricle margin of the yoke 70. More preferably, the cords 86 should be positioned for avoiding contact with the coronary vessels 30. The cords 86 vary in length such that the splint 54 and first ring 56

are oriented beneath the gel-filled cushion portion while the septum stent 52 and the first ring 56 are held stable in general alignment with the natural heart 10, and are generally not allowed to move away from the ventricular exterior wall when pressure is applied to a natural heart 10 via by activator 74.

5           As mentioned above, the present invention also includes an activator 74 attached to at least a portion of the yoke 70, preferably the apical portion 70a, as illustrated in Figures 5A and 5B. The activator 74 includes a lateral flexible arm 75 generally having an "L" shaped configuration that extends approximately two-thirds of the distance between the apical portion 70a and base portion 70b of the yoke 70.

10           Connected to the arm 75 is at least one, and preferably a plurality of, bands 84 extending away from the arm 75 sized and configured for placement adjacent the exterior surface of the natural heart 10. The distal ends of the bands 84 are typically affixed and secured along portions of yoke 70.

15           One embodiment of the yoke 70 and activator 74 is illustrated in Figure 5A in which the bands 84 extend perpendicularly away from the arm 75 and connect to the anterior and posterior portions of yoke 70. In another embodiment of the yoke 70 and activator 74 as illustrated in Figure 5B, bands 84 extend radially away from the distal end of the arm 75.

20           Referring now to Figures 7A and 7B, the activator 74 preferably has a hydraulic lateral arm 75 having a tubed-shape corrugated configuration with rings 77 affixed to the inner aspect of each corrugation. A plurality of longitudinally extending cords 76, preferably three or more, are affixed to the inner portion of arm 75, preferably the distal

end of arm 75 and also preferably to each of the rings 77. The cords 76 can vary in length, especially between the fixation points to each ring 77 for controlling the separation distance between rings 77. In fluid communication with the arm 75 via a driveline 92 is a pump unit "P", such as pneumatic or a hydraulic pump for controlling or altering the fluid volume within the arm 75.

Figure 7A illustrates the arm 75 in a relaxed condition when fluid pressure within arm 75 is at or below ambient levels and where the shape of arm 75 is determined by the external forces and the intrinsic stiffness of arm 75. To utilize the present invention, pressure within the arm 75 can be increased, preferably above ambient levels, so that the shape of the arm 75 is altered to an activated condition, as illustrated in Fig. 7B. The length difference of the various cords 76 between the rings 77 controls the radius of curvature of the arm 75 and the direction of curvature at various portions along the longitudinal length of the arm 75. The amount of pressure required within the arm 75 must be sufficient to overcome the intrinsic stiffness of the arm 75 at ambient condition, and to facilitate the proper deformation of both the arm 75 and bands 84 so that the proper amount of pressure is applied to the exterior wall of the natural heart 10 to assist in altering (i.e., reducing) the volume of one or more chamber of a natural heart 10 (e.g., the left ventricle 12) to maintain circulation of the blood through the circulatory system.

In a preferred embodiment, the arm 75 can be customized to apply different pressure to different portions of the natural heart 10. For example, varying the diameter of arm 75 along the longitudinal length can assist in controlling the curvature of arm 75. Regions of the arm 75 needing less bending moment can have a smaller diameter and



regions of the arm 75 where greater bending moments are preferred can have a larger diameter.

Various embodiments of an activator 74 can be utilized with the present invention to achieve a change in the volume of one or more heart chambers. It is noted that any  
5 activator 74 used with the present invention should be sufficient so that the cardiac output of a typical adult is between about 3 l/min and about 30 l/min, and preferably between about 5 l/min and 20 l/min.

In addition, there are various possible forces which can be used for activating, and thus altering the chamber volumes of the natural heart 10. The present invention can be  
10 utilized to flatten the exterior wall of the natural heart 10 in a plane substantially perpendicular to the plane of the atrioventricular valves (e.g., a mitral valve) or substantially parallel to the septum. When utilizing such a force, the activator 74 should be configured to produce a flexion in the convex direction limited to between about 2.5 to 3.0 times the curvature value of the exterior wall of the natural heart 10 during the  
15 diastolic portion of the cardiac cycle. Deflection in a concave direction is restricted only to those bands 84 extending away from the arm 75 and connecting to the base portion 70b of yoke 70.

Also, an activator 74 can be used to apply a uniform pressure to substantially the entire exterior wall of the natural heart 10.

20 Furthermore, the activator 74 can be used to indent the exterior wall of the natural heart 10 at more than one location, and preferably at two or three locations on either an exterior wall or the septum in a hemispheric or hemiellipsoid profile.

Additionally, an activator 74 can apply a torsion force to at least a part of the natural heart 10 at various angles.

In yet another embodiment, the activator 74 can apply a shearing force to a portion of the lateral exterior wall, which is directed apically and is a basal sheer force applied on the right side of the stint 52.

When the orientation of the arm 75 is altered from the relaxed condition, which is illustrated in Fig. 7A, to the activated condition, which is illustrated in Fig 7B, the arm 75 and the bands 84 deform and apply pressure against the exterior wall of the natural heart 10 for assisting with or facilitating activation of the natural heart 10 (the systolic portion of the cardiac cycle). As a result, the volume of one or more chambers of the natural heart 10 is reduced and blood is pumped out of the natural heart 10 and into the circulatory system.

Following the activation (i.e., systolic portion of the cardiac cycle), the arm 75 and bands 84 release from against the cardiac tissue and return to their relaxed condition. The combination of the stint 52 and the yoke 70 assists in returning the deformed portion of the natural heart 10 back to its pre-activation volume so that it can refill with blood during the diastolic portion of the cardiac cycle, so that the entire cardiac cycle can be repeated.

To position the device 50 into and around an existing natural heart 10, open heart thoracic surgery is required. Clinically, sufficient anesthesia is administered to the patient and the thoracic cavity is opened using standard thoracic procedures.

Once the thoracic cavity is opened, circulation of blood to the natural heart 10 must be bypassed so the present invention can be inserted into the patient. Referring initially to Fig. 2, the superior vena cava 26, the inferior vena cava (not shown), and aorta 26 are cannulated. The circulatory system is connected to a cardiopulmonary bypass machine so that circulation and oxidation of the blood are maintained during the procedure. By way of example, the procedure discussed in detail will be for insertion of the present invention to assist in the activation and operation of the left ventricle 12.

Through an aortotomy and an interatrial groove left atriotomy, the first and second rings 56 and 58, respectively, are inserted and sutured in position. Preferably, the first ring 56 is positioned suprajacent the mitral annuli and the second ring 58 is positioned subjacent the aortic annuli.

The interlocking struts of the septal frame 53 (e.g., anterior, posterior, basal struts) are inserted into the right ventricle 14 through an apical ventriculotomy, a right atriotomy with partial temporary detachment of the septal tricuspid leaflet of the tricuspid valve, and an outflow tract ventriculotomy, respectively. Suture strands are then passed back and forth against the interventricular septum, threading through loops to provide a septal splint 54. In placement of both the various struts of frame 53 and the strands that form splint 54, care is taken to maneuver behind chordae and behind or through major trabeculae and bases of papillary muscles. The suture strands are tied to form the net-like configuration of the septal splint 54 that lies snugly against the septum, but allows it to maintain normal rightward convexity. Separate connector elements 59, preferably pins,

are placed to joint the first ring 56 and the second ring 58, the second ring 58 and the septal splint 54, and the septal splint 54 and the first ring 56.

Next, the left pleural cavity is opened and the yoke 70 is positioned behind the natural heart 10. Cords 86 are assembled as 12" strands of suture with a polyester bead  
5 fused to one end and blunt straight needle on the other. Each suture is passed through a hole in the margin of the yoke 70, through the cardiac tissue, and preferably the ventricular wall, and through the internal stint 52 (i.e., first ring 56 or septal splint 54) and anchored after length adjustment, with the excess portion of the sutures cut and removed. Cords 86 are tightened to render the intrinsically flexible stint 52 relatively taut  
10 and control bulging, preferably in a rightwardly direction.

Cardiotomies are closed, and the activator 74 is attached to the yoke 70. The driveline 92 is attached to the drive unit "P" and all indicated monitoring lines are positioned. Preferably, Heparin-filled Teflon-coated polyurethane 5 Fr. catheters are brought through the posterior cervical incision into the chest and into the atrial  
15 appendages and an identical one into a branch of the innominate artery. Termination of a cardiopulmonary bypass is attempted and, if successful, the thoracotomy is closed.

An alternative method for positioning the present invention includes removing the natural heart 10 from the patient, positioning all the components of the present invention, as discussed above, and auto-transplanting the natural heart 10 back into the  
20 patient using standard cardiectomy and cardiac transplant techniques known in the industry.

Having shown and described the preferred embodiments to the present invention, further adaptations of the activation device for the living heart and method of deforming the living heart as described herein can be accomplished by appropriate modifications by one of ordinary skill in the art without departing from the scope of the present invention.

5 For example, the present invention can be used with any one or even a plurality of the various chambers of a living heart, and also could be used with different activators 74.

Other examples of an activator 74 usable with the present invention include a girdle assembly that can be activated by hydraulics forces or other forces, such as an electromagnetic for using magnets and electrical current. Several such potential  
10 modifications have been discussed and others will be apparent to those skilled in the art.

Accordingly, the scope of the present invention should be considered in terms of the following claims and is understood not to be limited in the details, structure and operation shown and described in its specification and drawings.

I claim:

1. A device for use with a natural heart for placement within the interior volume of a natural heart adjacent cardiac tissue thereof, said device comprising:  
  
a stint having a first ring for placement adjacent at least one of the atrioventricular annuli to stabilize and facilitate operation of the atrioventricular valve, and a second ring for placement adjacent at least one of the semilunar valve annuli to stabilize and facilitate operation of the semilunar valve.
2. The activation device of claim 1, wherein said stint comprises a septal splint to stabilize a septal wall of the natural heart.
3. The activation device of claim 1, wherein said stint comprises a connector element joining said first and second rings.
4. The activation device of claim 1, wherein said stint comprises a connector element joining said first ring and said splint.
5. The activation device of claim 1, wherein said stint comprises a connector element joining said second ring and said septal splint.

6. The activation device of claim 1, wherein said stint comprises a first connector element joining said first ring and said septal splint, and a second connector joining said second ring and said septal splint.
7. The activation device of claim 1, further comprising:
  - (a) a yoke for placement around a portion of the exterior surface of the natural heart in general alignment with said natural heart; and
  - (b) at least one cord connecting said stint to said yoke.
8. The activation device of claim 7, wherein said yoke is sized and configured for placement adjacent at least a portion of an atrioventricular groove of the natural heart.
9. The activation device of claim 7, wherein said yoke is sized and configured for placement adjacent at least a portion of an interventricular groove of the natural heart.
10. The activation device of claim 9, wherein said yoke is sized and configured for placement adjacent at least a portion of the anterior and posterior portions of said interventricular groove.

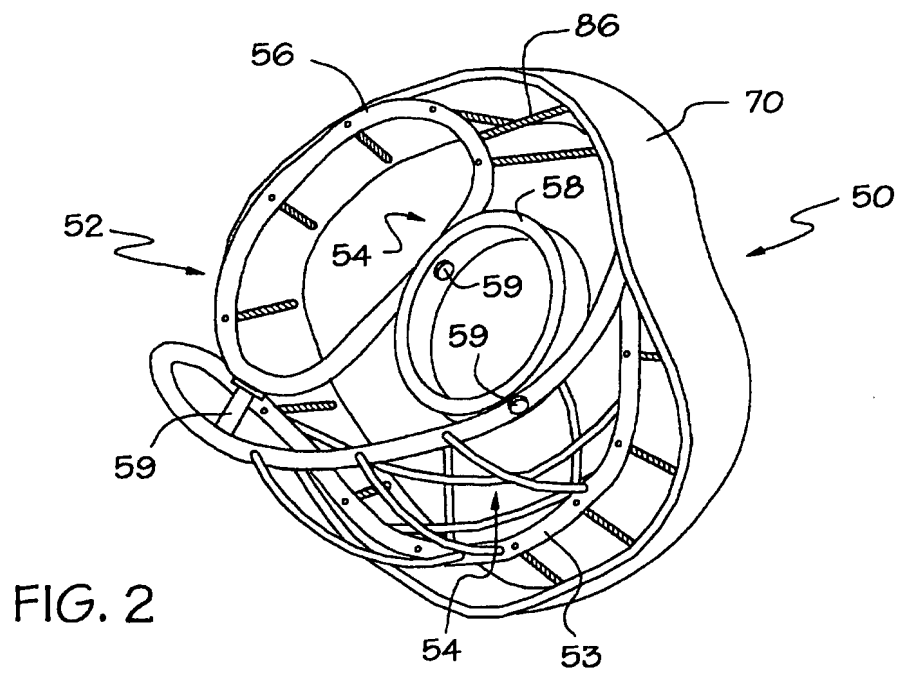
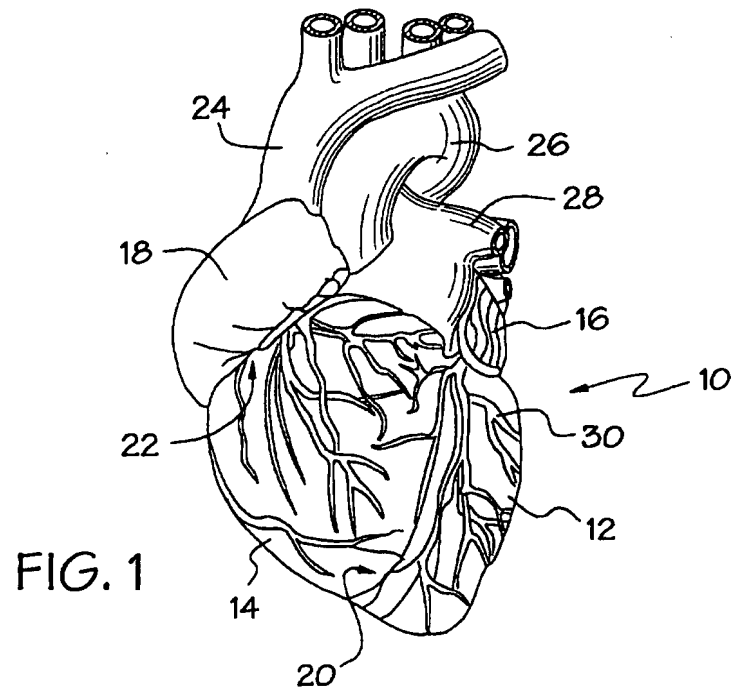
11. A mechanical ventricular activation device for use with a natural heart, said device comprising:
- (a) a stint for placement within the interior volume of a natural heart adjacent cardiac tissue thereof;
  - 5 (b) a yoke for placement around a portion of the exterior surface of the natural heart in general alignment with said natural heart;
  - (c) at least one cord connecting said stint to said yoke; and
  - (d) an activator attached to said yoke.
12. The device of claim 11, wherein said yoke comprises,  
an arm and;  
a plurality of bands connected to said arm.
13. The device of claim 12, wherein said plurality of bands extend away from said arm.
14. The device of claim 13, wherein said plurality of bands extend radially away from the distal end of said arm.
15. The device of claim 13, wherein said plurality of bands extend perpendicularly away from the distal end of said arm.



16. The device of claim 11, wherein said stint comprises a first ring for placement adjacent at least one of the atrioventricular annuli to stabilize and facilitate operation of a atrioventricular valve of the natural heart.
17. The device of claim 11, wherein said stint comprises a second for placement adjacent at least one of the semilunar annuli to stabilize and facilitate operation of a semilunar valve of the natural heart.
18. The device of claim 11, wherein said stint comprises a septal splint for stabilizing a septal wall of the natural heart.
19. The activation device of claim 11, wherein said stint comprises a connector element joining said first and second rings.
20. The device of claim 11, wherein said stint comprises a connector element joining said first ring and said splint.
21. The device of claim 11, wherein said stint comprises a connector element joining said second ring and said septal splint.

22. The activation device of claim 1, wherein said stint comprises a first connector element joining said first ring and said septal splint, and a second connector joining said second ring and said septal splint.
23. A method for mechanically deforming cardiac tissue, comprising the steps of:
- (a) providing a cardiac tissue activation device, further comprising a stint for placement along a portion of the interior surface of the cardiac tissue, a yoke for placement around a portion of the exterior surface of the cardiac tissue, at least one cord connecting said stint to said yoke, and an activator;
  - (b) deforming a portion of the cardiac tissue by movement of said stint; and
  - (c) releasing said activator from deforming said stint.
24. The method of claim 23, further comprising the step of repeating steps (b) and (c).
25. The method of claim 23, wherein step (b) comprises applying a torsion force to a portion of the cardiac tissue.
26. The method of claim 23, wherein step (b) comprises applying a shearing force to a portion of the cardiac tissue.

27. The method of claim 23, wherein step (b) comprises flattening a portion of the cardiac tissue.
28. The method of claim 23, wherein step (b) comprises applying a uniform pressure to the ventricular surface.



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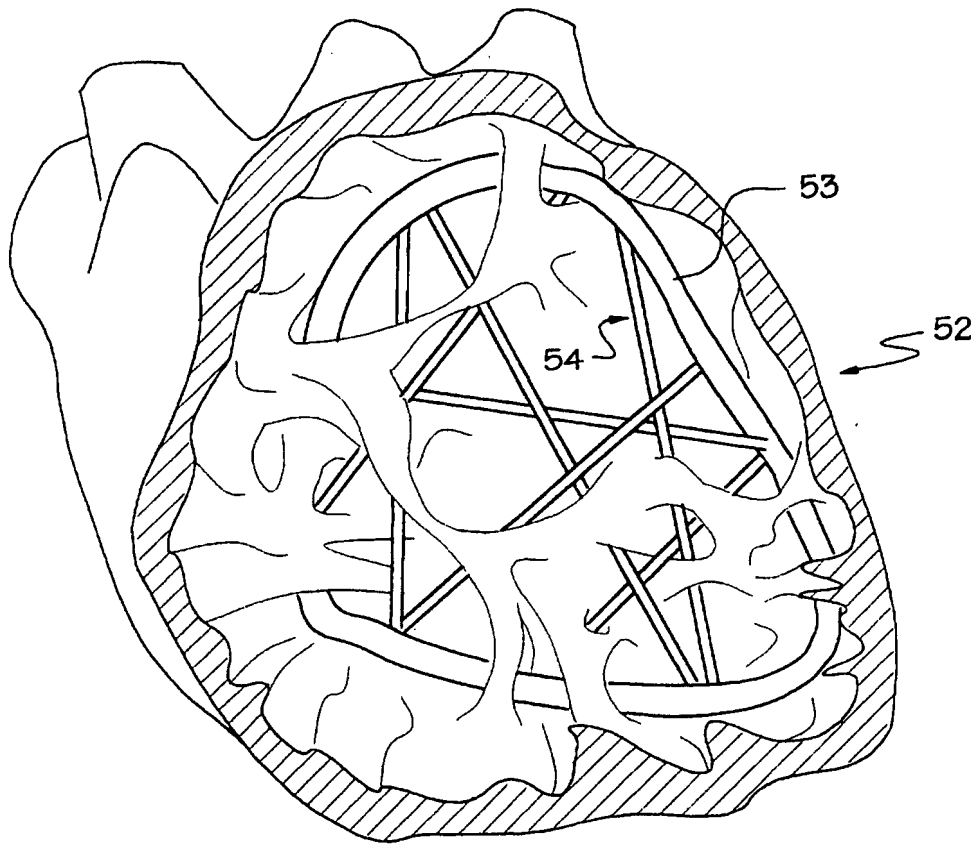


FIG. 3

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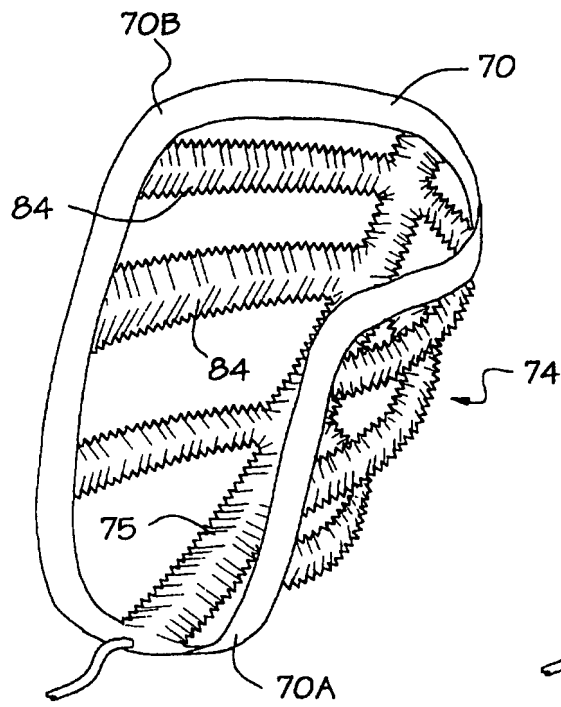


FIG. 5A

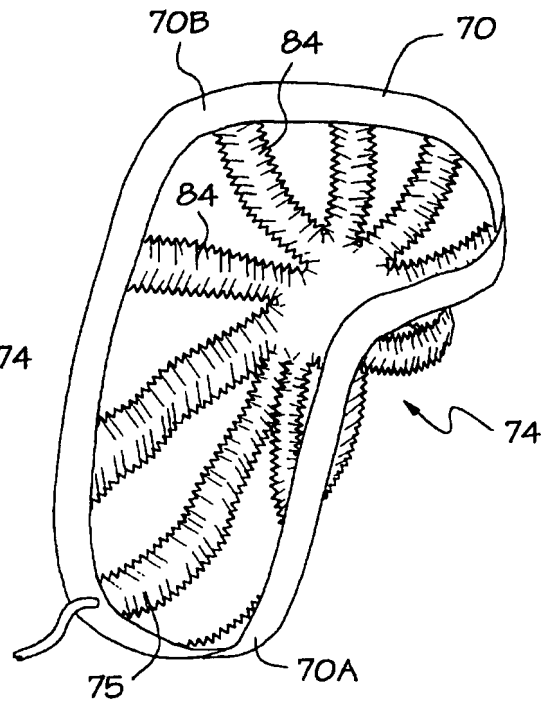


FIG. 5B

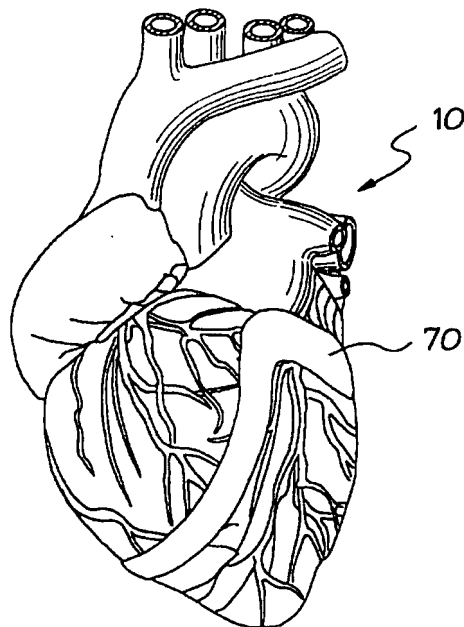


FIG. 4

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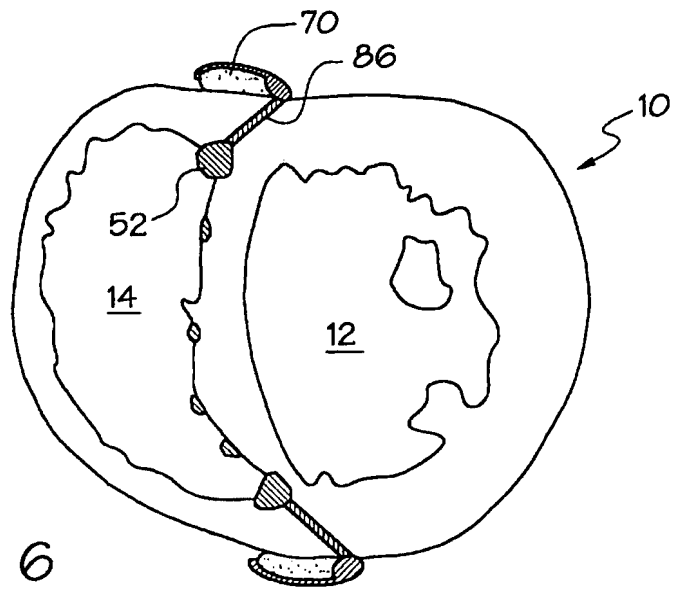


FIG. 6

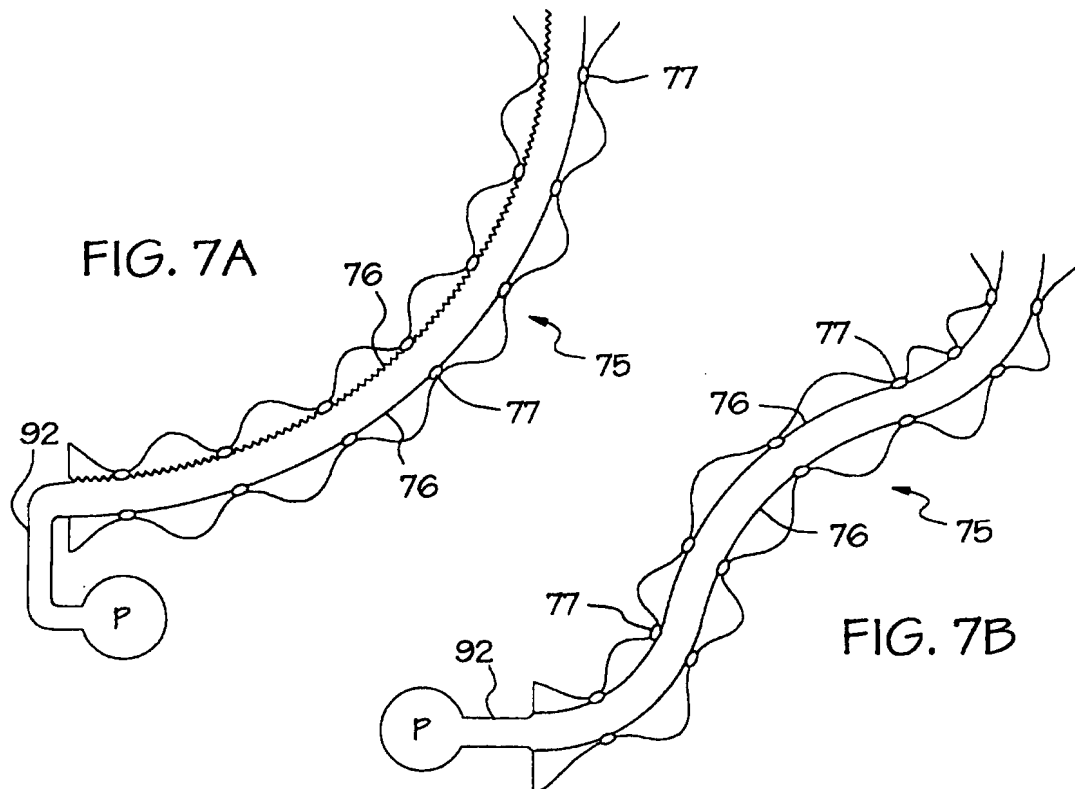


FIG. 7A

FIG. 7B

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/00374

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61H31/00

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61H A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 131 905 A (GROOTERS) 21 July 1992 see abstract; figures ---	11
A	US 4 536 893 A (PARRAVICINI) 27 August 1985 see column 2, line 49 - line 68; figures ---	11
A	US 5 201 880 A (WRIGHT ET AL.) 13 April 1993 see abstract; claim 1; figures ---	1,11
A	EP 0 119 357 A (HEMEX INC.) 26 September 1984 see abstract; figures -----	1,11

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*Z\* document member of the same patent family

Date of the actual completion of the international search

30 May 1997

Date of mailing of the international search report

04.06.97

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# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 97/00374

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 23-28  
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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 97/00374

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5131905 A	21-07-92	NONE	
US 4536893 A	27-08-85	DE 3307211 A	08-09-83
US 5201880 A	13-04-93	AU 670934 B	08-08-96
		AU 3597193 A	03-09-93
		CA 2127701 A	19-08-93
		EP 0624080 A	17-11-94
		WO 9315690 A	19-08-93
EP 119357 A	26-09-84	US 4535483 A	20-08-85
		AU 557515 B	24-12-86
		AU 2310484 A	19-07-84
		BR 8400148 A	21-08-84
		CA 1211254 A	16-09-86
		JP 59137051 A	06-08-84

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US97/12934

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 1/14

US CL : 604/4

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/4

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,308,320 A (SAFAR et al) 03 May 1994, entire document.	1-14
A,P	BATISTA et al, Partial Left Ventriculectomy to Improve Left Ventricular Function in End-Stage Heart Disease, Journal of Cardiac Surgery, November 1996, pages 96-98.	1-14
A	OZUNER et al, CREATION OF A PERICARDIAL WINDOW USING THORACOSCOPIC TECHNIQUES", SURGERY. Gynecology & Obstetrics, July 1992, Volume 175, pages 69-71.	1-14



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

06 NOVEMBER 1997

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# INTERNATIONAL SEARCH REPORT

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		AU 2310484 A	19-07-84
		BR 8400148 A	21-08-84
		CA 1211254 A	16-09-86
		JP 59137051 A	06-08-84



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification <sup>6</sup> : <b>A61M 1/14</b></p>	<p><b>A1</b></p>	<p>(11) International Publication Number: <b>WO 98/03213</b></p> <p>(43) International Publication Date: 29 January 1998 (29.01.98)</p>
<p>(21) International Application Number: PCT/US97/12934</p> <p>(22) International Filing Date: 23 July 1997 (23.07.97)</p> <p>(30) Priority Data: 08/685,262 23 July 1996 (23.07.96) US</p> <p>(71) Applicant: HEARTPORT, INC. [US/US]; 200 Chesapeake Drive, Redwood City, CA 94063 (US).</p> <p>(72) Inventors: STEVENS, John, H.; 727E Loma Verde Avenue, Palo Alto, CA 94303 (US). BOLDUC, Lee, R.; 761-1/2 Palo Alto Avenue, Mountain View, CA 94041 (US). BOYD, Stephen, W.; 333 Palomar Drive, Redwood City, CA 94062 (US). GIFFORD, Hanson, S., III; 3180 Woodside Road, Woodside, CA 94062 (US). DONLON, Brian, S.; 13944 Fremont Pines, Los Altos Hills, CA 94022 (US). HOULE, Philip, R.; Apartment #8, 525 Homer Avenue, Palo Alto, CA 94301 (US). ROSENMAN, Daniel, C.; 1415 Waller Street #3, San Francisco, CA 94117 (US).</p> <p>(74) Agents: HESLIN, James, M. et al.; Townsend and Townsend and Crew LLP, 8th floor, Two Embarcadero Center, San Francisco, CA 94111-3834 (US).</p>		<p>(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p><b>Published</b> With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</p>
<p>(54) Title: MINIMALLY-INVASIVE DEVICES AND METHODS FOR TREATMENT OF CONGESTIVE HEART FAILURE</p> <p>(57) Abstract</p> <p>A method of treatment of congestive heart failure comprises the steps of introducing an aortic occlusion catheter (26) through a patient's peripheral artery, the aortic occlusion catheter (26) having an occluding member (30) movable from a collapsed position to an expanded position; positioning the occluding member (30) in the patient's ascending aorta; moving the occluding member (30) from the collapsed shape to the expanded shape after the positioning step; introducing cardio-plegia fluid into the patient's coronary blood vessels to arrest the patient's heart; maintaining circulation of oxygenated blood through the patient's arterial system; and reshaping an outer wall of the patient's heart while the heart is arrested so as to reduce the transverse dimension of the left ventricle. The ascending aorta may be occluded and cardio-plegia fluid delivered by means of an occlusion balloon (44) attached to the distal end of an elongated catheter (42) positioned trans-luminal in the aorta from a femoral, subclavian, or other appropriate peripheral artery.</p>		

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5                   MINIMALLY-INVASIVE DEVICES AND METHODS FOR  
                  TREATMENT OF CONGESTIVE HEART FAILURE

                  BACKGROUND OF THE INVENTION

                  In congestive heart failure or CHF, the heart has  
10       become so enlarged as a result of viral infection, myocardial  
          infarction or other disease that it is unable to pump at a  
          sufficient rate to maintain adequate circulation of blood  
          throughout the body. As a result, blood backs up into the  
          lungs, causing shortness of breath and other symptoms, and, if  
15       left untreated, the disease can lead to death.

                  For some patients, the CHF may be treated  
          effectively with medication. However, in many cases, the  
          disease progresses to a point at which the patient requires a  
          heart transplant. Unfortunately, due to a donor shortage, of  
20       the 40,000 patients who may require a transplant each year,  
          only 2500 actually get one, with up to 15-20% of patients  
          dying while on the waiting list for a donor heart.

                  In response to the need for alternatives to  
          transplant for treating CHF, a surgical procedure has been  
25       tried in recent years known as the "Batista Operation" after  
          its developer, Dr. Randas J. V. Batista. In this procedure, a  
          large section of the left ventricular wall is excised from the  
          heart and the wall then sewn back together, thereby reducing  
          the transverse dimension and volume of the left ventricle, the  
30       primary pumping chamber of the heart. The reduced volume of  
          the ventricle permits less blood to be present in the chamber  
          during each of its contractions, thus reducing the forces  
          acting against the heart muscle as it contracts and allowing  
          the heart to pump more effectively.

35       Although the Batista Operation can extend the life  
          of a patient who would otherwise die without a transplant, it  
          is a highly invasive and traumatic procedure. In order to  
          expose the heart, the chest must be opened widely by sawing



the sternum in half and spreading apart the rib cage, known as a median sternotomy, producing a great deal of pain, risk of infection, and long recovery time. For elderly or extremely ill patients, the trauma produced by the operation could contribute significantly to the mortality and morbidity associated with procedure.

Moreover, the Batista Operation has typically been performed while the heart is beating, causing a great deal of blood loss through the ventricular incision, and risking the introduction of air into the bloodstream, potentially causing stroke or other neurological problems. To reduce blood loss and the risk of air embolism, the heart could be stopped and isolated from the rest of the circulatory system during the procedure by placing an external aortic cross-clamp on the ascending aorta and using conventional cardioplegia and cardiopulmonary bypass. However, because such cross-clamps crush the walls of the aorta together in order to occlude the vessel, cross-clamps may produce the added risk of releasing calcific particles from the inner walls of the aorta, which may embolize in the bloodstream and produce neurological events such as stroke. Moreover, the risk remains that air will become trapped in the ventricle after it has been closed, allowing the air to migrate to the brain as soon as the cross-clamp is removed. Conventional cross-clamps also require a large opening in the chest in order to gain access to the aorta, hindering any effort to reduce the trauma associated with the procedure.

What are needed, therefore, are devices and techniques for the surgical treatment of CHF which are less invasive and less risky than the Batista Operation, but which produce the benefits associated with reducing the volume of the left ventricle. The devices and techniques should facilitate the identification of an appropriate section of the left ventricular wall, excision or other reshaping of the section, and, if the section is removed, closure of the left ventricle, without requiring a gross thoracotomy or median sternotomy. If the left ventricle is opened, the devices and techniques should allow the patient to be placed on

cardiopulmonary bypass and the heart to be arrested and isolated from the circulatory system without the need for an external aortic cross-clamp. Further, the devices and techniques should minimize that risk that either air and other emboli will be produced by the procedure.

#### SUMMARY OF THE INVENTION

The invention provides devices and methods for treating CHF, as well as other diseases resulting in an enlarged heart, that not only significantly reduce the pain and trauma to the patient, but that may reduce the risk of infection and the risk of neurological events associated with the Batista Operation. The invention facilitates the reduction of left ventricular volume by removing a section of the heart wall or otherwise reshaping the ventricle without requiring a median sternotomy or gross thoracotomy. The invention further allows the procedure to be performed on cardiopulmonary bypass with the heart isolated and arrested, yet without the gross thoracic incision required by, or the risk of embolism produced by, conventional aortic cross-clamps. Moreover, the invention may significantly reduce the risk that air will be introduced into the bloodstream and embolized to the brain during or after the procedure.

In a first embodiment, the invention provides a method of reshaping a patient's heart, comprising the steps of:

introducing an aortic occlusion catheter through a patient's peripheral artery, the aortic occlusion catheter having an occluding member movable from a collapsed position to an expanded position;

positioning the occluding member in the patient's ascending aorta;

moving the occluding member from the collapsed shape to the expanded shape after the positioning step;

introducing cardioplegic fluid into the patient's coronary blood vessels to arrest the patient's heart;

maintaining circulation of oxygenated blood through the patient's arterial system; and

reshaping an outer wall of the patient's heart while the heart is arrested so as to reduce the transverse dimension of the left ventricle.

5 The ascending aorta is preferably occluded by means of an occlusion balloon attached to the distal end of an elongated catheter positioned transluminally in the aorta from a femoral, subclavian, or other appropriate peripheral artery. Cardioplegic fluid may then be delivered upstream of the occlusion balloon through a lumen in that catheter, and/or  
10 delivered in a retrograde manner through a separate catheter placed transluminally into the coronary sinus from a peripheral vein. While the heart is arrested, circulation of oxygenated blood is maintained preferably by peripheral extraporeal cardiopulmonary bypass (CPB), wherein blood is  
15 removed from a peripheral vein via a venous drainage catheter, filtered, oxygenated, and returned to a peripheral artery through an arterial return catheter.

By obviating the need for an aortic cross-clamp, the need for the median sternotomy through which such a cross-clamp is placed is also eliminated. The left ventricle may  
20 then be reshaped and volumetrically reduced using thoracoscopic instruments positioned through small incisions, punctures or ports located in the intercostal spaces between the ribs.

25 The invention further provides a method of reshaping a patient's heart comprising the steps of:

introducing a tissue attaching device into the patient's chest;  
engaging a first location on a wall of the left  
30 ventricle with the tissue attaching device; and  
manipulating the tissue attaching device to attach the first location to a second location on a wall of the heart so as to reduce the transverse dimension of the left ventricle, the user's hands remaining outside the patient's  
35 chest when manipulating the tissue attaching device.

In some embodiments, a section of the left ventricular wall is excised with a cutting device, then the left ventricle is closed using sutures, staples or other means

for wound approximation and closure, each applied using thoracoscopic instruments with the user's hands maintained generally outside of the chest. In other embodiments, a section of the left ventricular wall is gathered together or  
5 pursed outwardly or inwardly to produce one or more folds or pleats in the wall. These folds or pleats are then thoracoscopically sutured, stapled or otherwise fastened permanently in place to reduce the transverse dimension of the left ventricle.

10 In the method of the invention, the left ventricular wall may be approached in several different ways. In one approach, one or more small incisions, punctures, trocar sleeves, tissue retractors or other type of ports are placed in intercostal spaces in the left anterior and/or lateral side  
15 of the chest, preferably between the third and seventh intercostal spaces. This permits direct access to the outer wall of the left ventricle on the lateral and posterior sides of the heart, usually with minor retraction of the apex of the heart anteriorly using thoracoscopic graspers or other  
20 retraction instruments. The heart may then be viewed directly through an intercostal port, or by means of a thoracoscope positioned through an intercostal port to permit either direct or video-based viewing of the heart.

In a second approach, ports are placed are in the  
25 right lateral side of the chest between the third and seventh intercostal spaces. Approaching the heart from the right, an incision is then made in the left atrium on the posterior side of the heart, and the incision retracted to expose the mitral valve. The mitral valve apparatus is excised from the heart,  
30 providing access into the interior of the left ventricle through the mitral valve annulus. A thoracoscopic scissors or knife is then used to excise a portion of the left ventricular wall from the inside of the chamber, either under direct vision from a port in the right side of the chest, or under  
35 video-based vision using a thoracoscope positioned through a port into the heart. The procedure may be viewed from outside of the heart as well by placing a thoracoscope through a port in the left lateral or anterior side of the chest. The left

ventricular wall may then be closed using sutures, staples, or other means applied with an instrument introduced through the mitral annulus from the right chest, or through a port placed in the left lateral or anterior side of the chest as described  
5 above.

In still other embodiments, a restrictive girdle or band is placed around the outside of the heart to restrict the left ventricle to the desired diameter or volume. The band or girdle is preferably elastic so as to expand and contract with  
10 the heart as it pumps. Preferably, the girdle or band is applied to the heart using specialized thoracoscopic instruments placed through intercostal spaces in the rib cage while generally maintaining the user's hands outside the chest, thereby eliminating the need for a gross thoracotomy.

Because the chest is not grossly opened, the heart is isolated from the rest of the circulatory system, and in some embodiments, even the ventricle itself is not opened, the methods of the invention may reduce the risk that air will  
15 pass through the ventricular incision and into the bloodstream. To reduce this risk even further, the invention also allows the chest to be flooded with carbon dioxide or other suitable gas during the procedure to maintain the chest cavity free of air. A tube may be placed through one of the intercostal ports and gas delivered through the tube into the  
20 chest at a pressure suitable to ensure that air cannot enter the chest cavity. Additionally, trocar sleeves or tubular ports may be used which have internal seals like those used for gaseous insufflation in laparoscopic procedures, thereby preventing the unwanted introduction of air into the chest.  
25 Further, where some risk of air embolism is present due to the opening of the left ventricle, following closure the left ventricle and aorta may be flushed with saline and then vented through a lumen in the aortic occlusion catheter while maintaining aortic occlusion, thereby removing any trapped air  
30 that may be present.  
35

The nature and advantages of the invention will become more apparent in the following detailed description, taken in conjunction with the accompanying drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an anterior view of a patient's torso schematically illustrating the use of an endovascular cardiopulmonary bypass system according to the invention.

5           Figure 2 is an anterior view of a patient's chest illustrating the placement of intercostal ports and thoracoscopic instruments according to the invention.

          Figures 3-5 are posterior views of a patient's heart illustrating the removal of a section of the left ventricle and closure of the left ventricular wall according to the invention.

10

          Figure 6A is a transverse cross-section of a patient's chest illustrating an alternative approach to the left ventricle according to the invention.

15           Figure 6B is a transverse cross-section of a patient's chest illustrating an alternative method of ventricular volume reduction according to the invention.

          Figures 6C-6D are close-up cross-sections of the ventricular wall illustrating additional steps in the method of Figure 6B.

20

          Figures 7A-7B are transverse cross-sections of a patient's heart before and after treatment, respectively, illustrating the bifurcation of the left ventricle according to the invention.

25           Figure 7C is a posterior view of a patient's heart illustrating the exterior shape of the left ventricle after bifurcation as in Figure 7B.

          Figure 8A is a side view of a tissue gathering device according to the invention.

30           Figure 8B is a top view of the distal end of the tissue gathering device of Figure 8A.

          Figure 9A is a cross-section of a portion of the left ventricle illustrating the use of the tissue gathering device of Figure 8A according to the method of the invention.

35           Figure 9B is a posterior view of a patient's heart illustrating the heart after treatment using the tissue gathering device of Figure 8A.

Figure 10 is a posterior view of a patient's heart illustrating the use of a heart measurement device according to the invention.

5 Figure 11 is a transverse cross-section of a patient's thorax illustrating the use of a left ventricular measurement device according to the invention.

#### DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to Figure 1, an endovascular  
10 cardiopulmonary bypass (CPB) system useful in the method of the invention is illustrated as it is used in a patient. Additional aspects of such endovascular CPB systems suitable for use in the methods of the invention are described in the following patent applications, which are incorporated herein  
15 by reference: Serial No.08/282,192, filed July 28, 1994, Serial No.08/612,341, filed March 7, 1996, and Serial No. 08/486,216, filed June 7, 1995. The system includes a venous drainage cannula 20 placed into a femoral vein FV (or other suitable peripheral vein) and preferably having sufficient  
20 length to extend into the inferior vena cava IVC, the right atrium RA or the superior vena cava SVC. Venous drainage cannula 20 is connected to an extracorporeal CPB system 22, which filters and oxygenates the blood withdrawn from the patient. The system further includes an arterial return  
25 cannula 24 placed into a femoral artery FA (or other peripheral artery such as the subclavian) through which CPB system 22 pumps oxygenated blood into the arterial system. Arterial return cannula 24, venous drainage cannula 20 and CPB system 22 are configured to provide full cardiopulmonary  
30 bypass with the patient's heart arrested.

The endovascular CPB system further includes an aortic occlusion catheter 26 that is positioned into femoral artery FA through a port 28 at the proximal end of arterial return cannula 24. Port 28 has a hemostatic seal (not shown)  
35 to prevent blood loss when occlusion catheter 26 is positioned through the port. Occlusion catheter 26 has an occlusion balloon 30 at its distal end and a length sufficient to allow occlusion balloon 30 to be positioned in the ascending aorta

AA, usually at least about 80 cm. Occlusion catheter 26 preferably has at least three lumens, including an inflation lumen in communication with the interior of balloon 30 for delivery of an inflation fluid from a syringe 32 or other inflation device. A pressure lumen is also provided which communicates with a pressure port in the catheter distal to balloon 30, allowing pressure to be monitored by means of a pressure measuring device 34. Occlusion catheter 26 further includes a main lumen in communication with an additional port distal to balloon 30 to allow delivery of cardioplegic fluid from a cardioplegic fluid source 36 and to facilitate venting the aortic root by means of a suction pump 38. A two-way valve 40 permits selecting between cardioplegic fluid delivery or aortic root venting via the main lumen.

An optional component of the endovascular CPB system is a coronary sinus catheter 42 positioned transluminally into the coronary sinus CS via the internal jugular vein JV in the neck, the superior vena cava SVC, and right atrium RA. Coronary sinus catheter 42 permits retrograde delivery of cardioplegic fluid in conjunction with or instead of antegrade delivery through aortic occlusion catheter 26. The distal end of catheter 42 includes a balloon 44 configured to occlude the coronary sinus CS. Sinus catheter 42 has at least two lumens, including an inflation lumen in communication with balloon 44, and a delivery lumen in communication with a port distal to balloon 44 for delivering cardioplegic fluid into coronary sinus CS. A third lumen may optionally be provided for pressure measurement through a port distal to balloon 44.

As an additional option, an endovascular venting catheter may be introduced into a vein in the neck and advanced through the superior vena cava, the right atrium, the right ventricle and into the pulmonary artery for venting blood from the heart, as described in copending application Serial No. 08/415,238, filed March 30, 1995, which is incorporated herein by reference.

In use, with venous drainage cannula 20 and arterial return cannula 24 in place and blood circulating through extracorporeal CPB system 22, aortic occlusion catheter 26 is



inserted through arterial return cannula 24 and slidably advanced toward the heart until occlusion balloon 30 is in the ascending aorta AA. Balloon 30 is then inflated to fully occlude the aortic lumen between the coronary ostia (not shown) and the brachiocephalic artery BA. Cardioplegic fluid, usually consisting of a cold potassium chloride solution mixed with oxygenated blood, is then delivered into the ascending aorta through the main lumen of occlusion catheter 26, from which it flows into coronary arteries and perfuses the myocardium, stopping cardiac contractions. If coronary sinus catheter 42 is utilized, balloon 44 may be inflated and cardioplegic fluid delivered into the coronary sinus CS, from which it flows through the coronary veins to perfuse the myocardium. Between periodic infusions of cardioplegic fluid, valve 40 is switched to allow the aortic root to be vented of fluid via occlusion catheter 26. Aortic root pressure may be continuously monitored using pressure measurement device 34.

Prior to arresting the heart, it may be desirable to perform a number of surgical steps in the operation up to the point of actually cutting into the myocardium so as to minimize the time for which the heart is stopped. A number of surgical ports 50, usually between about one and six, are placed in intercostal spaces IS between the ribs R. These ports may be simple plastic tubes having flanges at their proximal ends to prevent passage entirely into the chest and having sufficient rigidity to retract intercostal tissue so as to form an opening. Trocar sleeves or small bladed rib retractors may also be used. A soft tissue retractor that may be particularly useful in the method of the invention is described in application Serial No. 08/610,619, filed March 4, 1996, which is incorporated herein by reference. In some cases, instruments may be placed directly through incisions or punctures between the ribs without any type of retraction. In any case, all of the aforementioned means of access into the chest will be referred to herein as ports.

Ports 50 may be positioned in any of several regions of the chest, depending upon the desired approach to heart. For approaching the left ventricle on the posterior side of

the heart, ports 50 are preferably placed in the fourth, fifth, sixth or seventh intercostal spaces on the left anterior and/or left lateral side of the patient's chest. For approaching the left ventricle from within the heart via the left atrium and the mitral valve, ports 50 are placed in the right lateral side of the chest in the second, third, fourth, fifth, or sixth intercostal spaces. Of course, it will be understood that the exact location of ports 50 will depend upon the location of the surgical site on the heart, individual patient anatomy, and surgeon preference.

One or both of the patient's lungs may have to be partially or fully collapsed during the procedure in order to gain access to the heart. With the lungs collapsed, the pericardium PC is incised, as illustrated in Figure 2, using thoracoscopic scissors 52, an electrocautery probe or other appropriate cutting devices, along with graspers 54 or other retraction devices, inserted through ports 50. Suitable instruments are described in US patent No. 5,501,698, which is incorporated herein by reference. A thoracoscope 56 is inserted through one of ports 50 to facilitate visualization. Thoracoscope 56 includes a camera 58 which produces a video image of the interior of the chest that can be viewed on a video monitor (not shown). Various conventional thorascopes may be used, including the articulating Welch-Allyn DistalView 360 (Welch-Allyn, Skaneateles Falls, NY), or a 30° angled endoscope available from Olympus Optical (Lake Success, NY). The surgeon may also look directly into the chest through ports 50, assisted by illumination of the chest by means of a light probe inserted through a port. The pericardium is opened or removed from around the left ventricle to expose the surgical site.

In a first embodiment of the ventricular volume reduction procedure of the invention, a portion of an outer wall of the left ventricle is removed and the wall then re-closed so as to reduce the traverse dimension and volume of the ventricular chamber. Referring to Figure 3, a posterior view of the heart, with the patient's heart arrested and circulation maintained by CPB system 22, a cutting device such

as a knife 60 along with thoracoscopic graspers 62 are inserted through ports 50 and used to excise the desired portion of the ventricular wall. During the procedure some retraction of the heart may be required, by for example, grasping the apex of the heart with graspers 62 and moving the apex anteriorly so as to expose the posterior aspect of the left ventricle. Using knife 60, a stab wound is made near the apex AP of the heart and an incision extended superiorly toward the left atrium in an arc bowing outwardly toward the left side of the heart. A second incision is made from the apex in an opposing arc bowing outwardly toward the right side of the heart and intersecting the first incision near the coronary sinus CS, allowing a football-shaped section of myocardial tissue to be removed. This leaves an opening OP in the left ventricular wall as illustrated in Figure 4.

Opening OP is then sutured closed using thoracoscopic needle drivers 64 to drive curved needle 66 and suture 68 through ventricular wall VW and using graspers 62 to assist in approximating the opposing edges of the opening. Usually a relatively coarse running stitch is placed in the wall to draw opening OP closed, and a finer running stitch is then applied to ensure the wound is hemostatically sealed.

The exact location and amount of tissue removed from the left ventricular wall will vary according to the type and severity of disease and other factors. The effectiveness of the heart in pumping blood will generally be increased by reducing the transverse dimension of the left ventricle so as to reduce the overall volume of the chamber. This allows less blood to flow into the left ventricle before each contraction, thereby reducing the outward force of the blood against the ventricle when it contracts. Preferably, a sufficiently large section of the ventricular wall will be removed to reduce the ventricle to having a transverse dimension (generally perpendicular to the interventricular septum) on the order of 4 to 7 cm.

Generally, opening OP in the left ventricular wall will be formed between the anterior and posterior papillary muscles, avoiding unnecessary damage to the mitral valve

apparatus. In some cases, however, the mitral valve apparatus is damaged or removed during the procedure, requiring replacement or repair of the valve following removal of the ventricular wall section. This may be accomplished by  
5 introducing an annuloplasty ring or prosthetic valve into the heart through ports 50 and opening OP and securing the prosthesis at the mitral valve position using thoracoscopic instruments introduced through ports 50. Alternatively, the mitral valve may be replaced via ports in the right lateral  
10 side of the chest by entering the left atrium, using the techniques described in copending application Serial No. 08/465,383, filed June 5, 1995, which is hereby incorporated herein by reference.

Following closure of the left ventricular wall,  
15 ports 50 are removed and thoracic incisions are closed. Cardioplegic fluid infusions are discontinued and the aortic root is vented through occlusion catheter 26 to remove any air or other particles which may be present in the heart or aorta. If desired, saline may be delivered through the main lumen of  
20 the occlusion catheter into the aortic root, or a small catheter may be advanced through the occlusion catheter and into the left atrium through the aortic valve to deliver saline into the left ventricle. The heart may be compressed using thoracoscopic probes to urge air out of the left  
25 ventricle. The saline is then vented through occlusion catheter 26 to remove air and other emboli. In order to restart heart contractions, occlusion balloon 30 on aortic occlusion catheter 26 is deflated to allow blood from arterial return cannula 24 to reach the coronary ostia. If cardiac  
30 contractions do not resume spontaneously, an electric shock may be delivered to the heart using thoracoscopic or external defibrillation paddles. When the heart is in sinus rhythm, the patient is weaned from cardiopulmonary bypass, vascular punctures are closed, and the patient recovered from general  
35 anesthesia.

Because the left ventricle is opened during the procedure, it will be desirable to keep air out of the chest cavity to the maximum extent until the ventricle is closed.

For this purpose, ports 50 may be provided with gaseous seals like those used in laparoscopic trocar sleeves to maintain an air-free environment within the chest. In addition, a gas such as carbon dioxide that is not likely to embolize in the blood stream may be delivered into the chest at a sufficient rate and pressure to prevent air from entering. Other techniques for preventing air embolism are described in copending application Serial No. 08/585,871, filed January 12, 1996, which is incorporated herein by reference.

Figure 6A-6D are transverse cross-sections of a patient's thorax and heart illustrating additional embodiments of the method of the invention. In these embodiments, a right chest approach is used similar to that described in copending application Serial No. 08/465,383 which has been incorporated herein by reference. That application describes techniques for opening the pericardium, forming and retracting an atrial incision, removing the mitral valve, and implanting a valve prosthesis which may be utilized in the method of the present invention.

Preferably, ports 50A are placed in the second, third, fourth, fifth, or sixth intercostal spaces in the right lateral side of the chest. Optionally, additional ports 50B may be placed in the left lateral or left anterior sides of the chest to approach the left ventricle on the posterior side of the heart, as described above with reference to Figures 1-2. An opening is first formed in the pericardium using thoracoscopic instruments inserted through right chest ports 50A and/or left chest ports 50B so as to expose the left atrium LA and the left ventricle LV. A thoracoscope 70 may be inserted through one of ports 50A to view the interior of the chest, or the surgeon may view the chest cavity directly by looking through ports 50A. If desired, one or more of ports 50A may be configured to provide a wider opening into the chest to allow greater maneuverability of instruments and to facilitate direct vision into the chest, such as the oval-shaped port described in application Serial No. 08/465,383, or the soft tissue retractor described in application Serial No. 08/610,619, referenced above. Preferably, these will not

require cutting or removing the ribs, and will minimize any retraction of the ribs, although in some cases it may be desirable to retract the ribs slightly or remove a small portion of a rib to provide greater access into the chest.

5 However, ports 50A will generally not be large enough to allow the surgeon's hands to be placed into the chest, although it may be possible to place one or more individual fingers into the chest.

10 The right lung is collapsed, the pericardium is opened and the patient is on CPB with the heart arrested as described above. An incision is made in the left atrium on the right lateral/posterior aspect of the heart using thoracoscopic scissors or knife inserted through a port 50A. The atrial incision is then retracted anteriorly using a  
15 thoracoscopic retractor 72. Suitable retractors are described in copending application Serial No. 08/577,547, filed December 22, 1995 which is hereby incorporated herein by reference. With the atrial incision retracted in this manner, the mitral valve is exposed at a direct line of sight from a port 50A in  
20 the fourth, fifth, or sixth intercostal space in the right chest. The mitral valve leaflets may then be removed using thoracoscopic scissors so that the left ventricle LV is visible through the mitral valve annulus VA. The valve leaflets and chordae tendonae may alternatively be left  
25 intact, and a thoracoscope introduced through the valve into left ventricle LV to provide visualization within the chamber.

In the embodiment shown in Figure 6A, a section of the left ventricular wall VW is then removed using elongated thoracoscopic scissors 74 or other suitable cutting device  
30 introduced through a port 50A and valve annulus VA. Scissors 74 are used to excise a football-shaped section of ventricular wall tissue, preferably between the anterior and posterior papillary muscles. An additional thoracoscope 76 may be introduced through left lateral chest ports 50B with the left  
35 lung collapsed to visualize the outer wall of the left ventricle to ensure the desired section is removed without cutting into adjacent tissues.

The left ventricular wall is then closed in one of two ways. Ventricular wall VW may be sutured from within the chamber with thoracoscopic needle drivers introduced through right chest ports 50A and mitral valve annulus VA, or sutured from outside the heart using needle drivers inserted through left chest ports 50B as described above in connection with Figure 5. Advantageously, should the mitral valve require repair or replacement after the ventricular wall has been closed, excellent access is provided through right chest ports 50A to implant either a replacement valve or an annuloplasty ring, or perform any necessary surgical repair of the valve, in the manner described in copending application Serial No. 08/465,383, already incorporated herein by reference. The left atrium is then closed. Ports 50A, 50B are removed and thoracic incisions are closed. The heart is restarted and the patient is weaned from cardiopulmonary bypass as described above.

In an alternative embodiment, shown in Figures 6B-6D, rather than cutting entirely through the heart wall to remove a section of the wall, a section of the inner wall of the heart is removed while leaving a thin layer of the outer wall intact. For this purpose, a thoracoscopic tissue-removing instrument 61, such as an end-biting biopsy or rongeur type instrument, may be utilized which has a pair of pivotable jaws 63 with tissue-cutting cup-shaped tips 65 that interact in a shearing relationship to bite off a portion of tissue, as shown in Figure 6C. A variety of other conventional endoscopic tissue removal instruments may also be used. In this way, a very thin section of the ventricular wall is created in the area which would otherwise be removed according to the alternative methods described above. Ventricular wall VW is then drawn together and sutured so that the thin section of the wall is pursed outward, as shown in Figure 6D. A thoracoscopic needle driver 67 may be inserted through a right chest port 50A and through the mitral valve to apply a suture 69, or a needle driver may be inserted through a left lateral or anterior port 50B to apply sutures from the exterior of the heart. In some cases, it may be desirable to

progressively draw the heart wall closer and closer together, by first drawing together only a portion of the thin-walled section and suturing it in place, then drawing together a wider portion, suturing it, and repeating the process until  
5 the entire thin-walled section has been folded together and the ventricle is of the desired dimension.

Figures 7A-7C illustrate a further embodiment of the method of the invention. In this embodiment, rather than removing a section of the left ventricle, the ventricle is  
10 reshaped by attaching a central longitudinal section of the ventricular wall VW to the interventricular septum IS. This is most readily accomplished by inserting a thoracoscopic tissue attachment device through left chest ports 50B (Figure 2), exerting inward pressure against the left ventricular wall  
15 VW until it abuts septum IS, and securing wall VW to septum IS. The tissue attachment device comprises, in an exemplary embodiment, an insertion device 71 for applying a T-shaped fastener like that described in reissued US Patent No. Re34,021, incorporated herein by reference. Insertion device  
20 71 has a tubular shaft 73 with a sharpened distal end 75 used to penetrate ventricular wall VW and interventricular septum IS. A suture 77 is attached to a central portion of a fastener 80 (not shown in Fig. 7A) which is removably positioned in tubular shaft 73 during insertion. A second  
25 suture 79 is also attached to an end of fastener 80 for removal purposes, as described in the forementioned reissue patent. Once distal end 75 has penetrated system IS, an obturator (not shown) is positioned through tubular shaft 73 so as to deploy fastener 80 into the right ventricle RV.  
30 Insertion device 71 is then removed from the heart, leaving sutures 77,79 extending through the septum IS and ventricular wall VW. A retainer 81, slidably mounted on sutures 77,79, is then advanced against ventricular wall VW to urge the ventricular wall against septum IS, as shown in Fig. 7B. A  
35 series of fasteners 80 are applied in this way along a generally vertical line extending from the apex of the heart toward the superior aspect of the heart so as to bifurcate the ventricle into two separate chambers communicating with each



other and with the aortic valve AV and mitral valve MV at the superior end of the chambers. Each of the smaller chambers thus created has a smaller transverse dimension and volume than the left ventricle, and the contraction of each chamber is therefore opposed by a smaller outward force from blood present in the chamber than that to which the single larger ventricle is subject. It will be understood that a variety of tissue attachment techniques may be used instead of the T-shaped fastener illustrated, including suturing by means of a large curved needle and thoracoscopic needle drivers, or skin or fascia type staplers. A particular advantage of this technique is that it does not require the left ventricle to be opened and exposed to air, thereby eliminating the risk of air embolism resulting from the procedure. Additionally, the technique avoids any loss of blood from the ventricle, allowing it to be performed on the beating heart, without occluding the aorta, arresting the heart, or placing the patient on CPB.

A further embodiment of a method of ventricular volume reduction will now be described in connection with Figures 8A-8B and 9A-9B. In this embodiment, a thoracoscopic tissue gathering device is utilized, an exemplary embodiment of which is illustrated in Figures 8A-8B. Tissue gathering device 84 comprises an elongated tubular shaft 86 and an inner rod 88 extending slidably through shaft 86. A tissue engaging member 90 is attached to the distal end of rod 88. Tissue engaging member 90 comprises a pair of jaws 92 biased away from each other and connected at their proximal ends to rod 88. The lateral surfaces 94 of jaws 92 are engaged by the inner wall of shaft 86 such that sliding the shaft distally relative to rod 88 urges jaws 92 toward one another. A plurality of sharp points or teeth 96 extend inwardly from a distal portion of jaws 92 and are configured to penetrate the ventricular wall, as described below. Jaws 92 may be as narrow as the diameter of shaft 86 or even narrower, if desired, with only one or two opposing teeth 96, but are preferably somewhat wider as illustrated, e.g. 1-5 cm in width (transverse to shaft 86), with three or more teeth 96 on each

jaw, to facilitate gathering a wide section of tissue between them. The distal transverse portion 97 of jaws 92 on which teeth 96 are disposed is preferably arcuate in shape to facilitate grasping a curved section of tissue between the jaws.

5 A handle 98 is attached to the proximal end of shaft 86 and includes a stationary handle member 100 having finger loops 101 and a movable handle member 102 pivotably attached to stationary handle member 100 and having thumb loop 103.

10 The proximal end of rod 88 is attached to movable handle member 102 such that pivoting the movable handle member toward the stationary handle member pulls rod 88 proximally relative to shaft 86, thereby closing jaws 92. A locking mechanism 104 facilitates maintaining the jaws in the closed position

15 without maintaining pressure on handle 100.

The use of tissue gathering device 84 in the method of the invention is illustrated in Figures 9A-9B. Tissue gathering device 84 is introduced through a port 50B (Figure 2) in the left lateral or anterior side of the chest selected

20 to allow access to the left ventricle on the posterior side of the heart near the apex. The heart may be retracted as necessary to facilitate access and visualization of the left ventricle either directly or by means of a thoracoscope. Jaws 92 are positioned in the open position against the ventricular wall VW and closed so as to gather a section of ventricular

25 wall tissue between the jaws, as illustrated in Figure 9A. Usually this will be an arcuate section of tissue extending from a point near the apex superiorly along the left ventricle on the posterior side of the heart. Points 96 penetrate the

30 outer surface of the ventricular wall to facilitate grasping the wall tissue and pursing it outwardly between the jaws. Locking mechanism 104 on handle 100 may then be engaged so as to lock jaws 92 in position, thereby maintaining the gathered section of ventricular wall tissue between jaws 92.

35 The opposing halves of the folded section of wall tissue are then attached to one another near the base of the fold, using a large arcuate needle 108 attached to a suture 110, driven by a thoracoscopic needle driver 112 inserted

through a port 50. A running stitch may be applied, or a series of individual suture loops. Alternatively, a thoracoscopic stapler, T-fastener applier, or other suitable tissue fastening device may be used. The result is shown in Figure 9B. A large section FS of left ventricle LV has been folded outwardly and isolated from the remainder of the ventricle, thereby reducing the transverse dimension and volume of the ventricle. If desired, the outer portion of the folded section FS may be cut off and removed using a thoracoscopic scissors or knife. Advantageously, as in the embodiment described above in reference to Figures 7A-7C, the left ventricle is not opened during the procedure, eliminating the risk of air embolism, and avoiding blood loss, thus allowing the procedure to be performed on a beating heart without cardiac arrest and CPB.

In any of the embodiments of the invention described herein it may be desirable to more accurately measure the size of the left ventricle to allow a more precise determination of the amount by which the left ventricle must be reduced. Figures 10 and 11 illustrate two alternative embodiments for measuring left ventricular size. In Figure 10, a thoracoscopic heart measurement device 120 comprises a shaft 122 configured for insertion through a thoracic port between the ribs, and a flexible band 124 extending from the distal end of the shaft to form a loop. Band 124 may be made of a flexible polymer or metal, and extends slidably through an inner lumen in shaft 122 so that the size of the loop may be contracted or expanded by extending or retracting band 124 from the distal end of the shaft. In this way, the loop may be placed around the exterior of the heart H and cinched against the outer wall of the heart. Measurement device 120 is then removed from the chest while maintaining the size of the loop, which may then be measured outside the chest to determine the circumference or diameter of the heart.

An alternative embodiment of a ventricular measurement device 130 is illustrated in Figure 11. Ventricular measurement device 130 includes a shaft 132 positionable through a right chest port 50A, through a left

atrial incision, through the mitral valve, and into the left ventricle LV. Shaft 132 therefore has a length of at least about 20 cm, and usually about 25-40 cm. An elastomeric balloon 134 is attached to the distal end of shaft 132 and has an interior in communication with an inflation lumen extending through shaft 132. An inflation device such as a syringe 136 is attached to the proximal end of shaft 132 in communication with the inflation lumen to facilitate delivery of an inflation fluid into balloon 134. Balloon 134 is of a size large enough to completely occupy the left ventricle, preferably being inflatable to a diameter of 4-12 cm. In this way, measurement device 130 may be introduced into the left ventricle via the left atrium and mitral valve and balloon 134 expanded until it engages the inner ventricular wall. By observing the volume of inflation fluid required to expand the balloon to this size, the approximate volume of the left ventricle may be assessed. In an alternative embodiment, a penetration may be made in the wall of the left ventricle via a port in the left lateral or anterior side of the chest, and balloon 134 inserted directly through the penetration to measure left ventricular volume. A purse string suture may be placed in the heart wall around the penetration to maintain hemostasis around shaft 132.

While the above is a complete description of the preferred embodiments of the invention, it will be understood that various substitutions, modifications, alternatives, and additions will be possible without departing from the scope of the invention, which is defined by the appended claims.

WHAT IS CLAIMED IS:

1                   1.    A method of reshaping a patient's heart,  
2    comprising the steps of:  
3                    introducing an aortic occlusion catheter through a  
4    patient's peripheral artery, the aortic occlusion catheter  
5    having an occluding member movable from a collapsed position  
6    to an expanded position;  
7                    positioning the occluding member in the patient's  
8    ascending aorta;  
9                    moving the occluding member from the collapsed shape  
10   to the expanded shape after the positioning step;  
11                   introducing cardioplegic fluid into the patient's  
12   coronary blood vessels to arrest the patient's heart;  
13                   maintaining circulation of oxygenated blood through  
14   the patient's arterial system; and  
15                   reshaping an outer wall of the patient's heart while  
16   the heart is arrested so as to reduce the transverse dimension  
1   of the left ventricle.

1                   2.    The method of claim 1, wherein the reshaping  
2    step is carried out by:  
3                    removing a portion of a wall of the patient's left  
4    ventricle; and  
5                    closing an opening created by the portion.

1                   3.    The method of claim 1, wherein:  
2                    the positioning step is carried out with the  
3    occluding member being mounted to a catheter having a lumen  
4    therethrough; and  
5                    the introducing step is carried out with the  
6    cardioplegic fluid passing through the lumen in the catheter.

1                   4.    The method of claim 3, further comprising the  
2    steps of:  
3                    introducing a tissue attaching device into the  
4    patient's chest;

5           engaging a first location on a wall of the left  
6   ventricle with the tissue attaching device; and  
7           manipulating the tissue attaching device to attach  
8   the first location to a second location on a wall of the heart  
9   so as to reduce the transverse dimension of the left  
10   ventricle.

1           5.    The method of claim 4, wherein:  
2           the introducing step is carried out with the tissue  
3   attaching device extending between adjacent ribs in the  
4   patient.

1           6.    A method of reshaping a patient's heart muscle,  
2   comprising the steps of:  
3           introducing a tissue attaching device into the  
4   patient's chest;  
5           engaging a first location on a wall of the patient's  
6   left ventricle with the tissue attaching device; and  
7           manipulating the tissue attaching device to attach  
8   the first location to a second location on a wall of the heart  
9   so as to reduce the transverse dimension of the left  
10   ventricle, the user's hands remaining outside the patient's  
11   chest when manipulating the tissue attaching device.

1           7.    The method of claim 6, further comprising the  
2   steps of:  
3           introducing a cutter into the patient's chest, the  
4   cutter having a manually operable actuator;  
5           cutting a portion of a patient's left ventricle from  
6   the heart with the cutter, the user's hands being outside the  
7   patient's chest when actuating the manually operable actuator;  
8   and  
9           removing the portion of the patient's heart muscle;  
10          the manipulating step being carried out to close an  
11   opening in the patient's heart formed by the removing step.

1           8.    The method of claim 7, wherein:

2           the introducing steps are carried out by passing the  
3   cutter and tissue attaching device between adjacent ribs.

1           9.   The method of claim 6, wherein:  
2           the manipulating step is carried out without cutting  
3   through the wall of the heart.

1           10.  The method of claim 6, wherein:  
2           the manipulating step comprises folding a section of  
3   the heart wall between the first and second locations so as to  
4   reduce the size of the left ventricle.

1           11.  The method of claim 6, wherein:  
2           the manipulating step comprises attaching a portion  
3   of the left ventricular wall to the interventricular septum.

1           12.  The method of claim 6, further comprising  
2   measuring the size of the left ventricle before the step of  
3   manipulating using a sizing instrument introduced into the  
4   chest while maintaining the hands outside the chest.

1           13.  The method of claim 6, wherein:  
2           the manipulating step is carried out while viewing  
3   the heart using a viewing scope.

1           14.  The method of claim 6, wherein:  
2           each of said steps is carried out while maintaining  
3   the patient's ribs and sternum intact.

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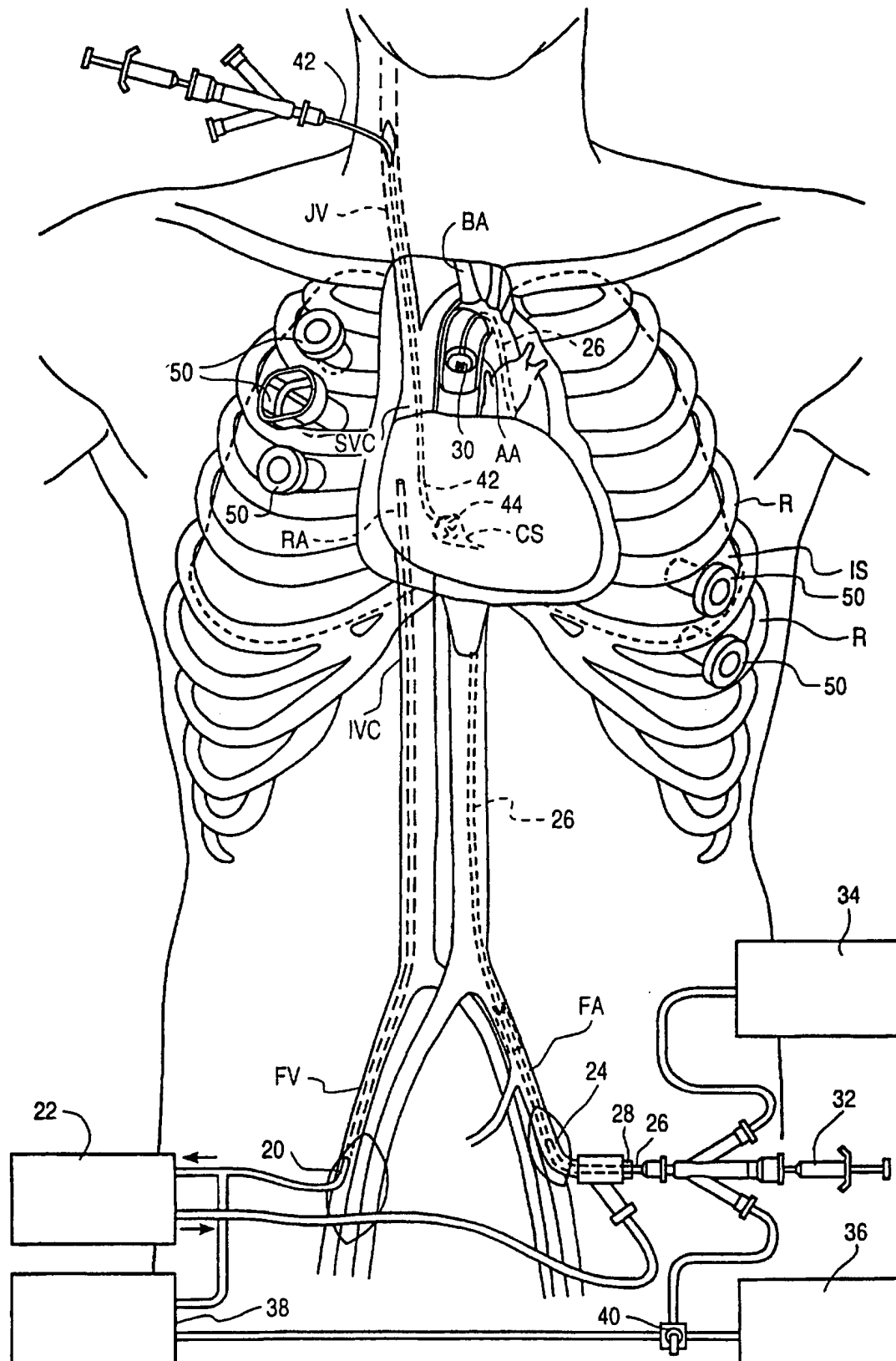


FIG. 1

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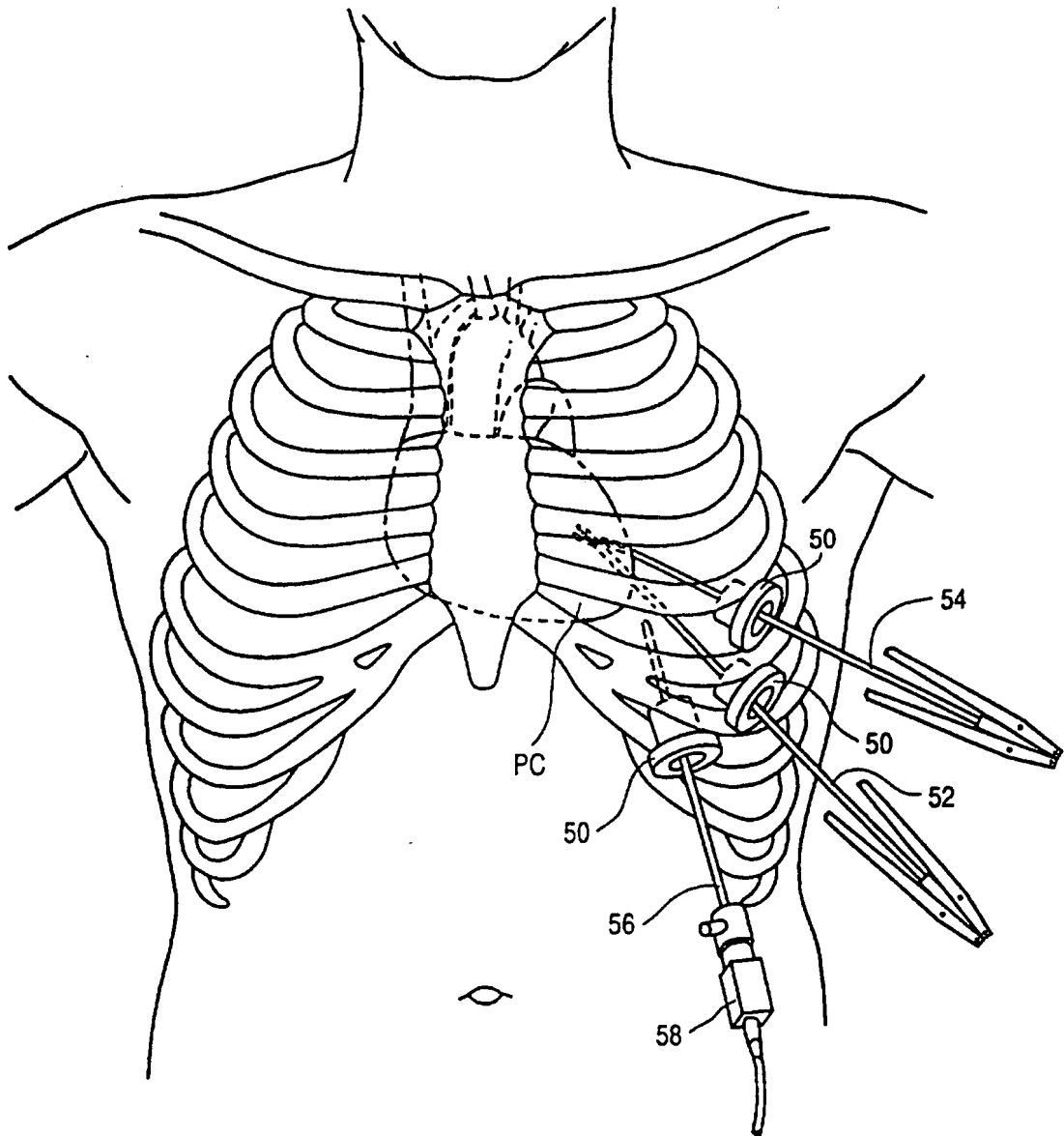


FIG. 2

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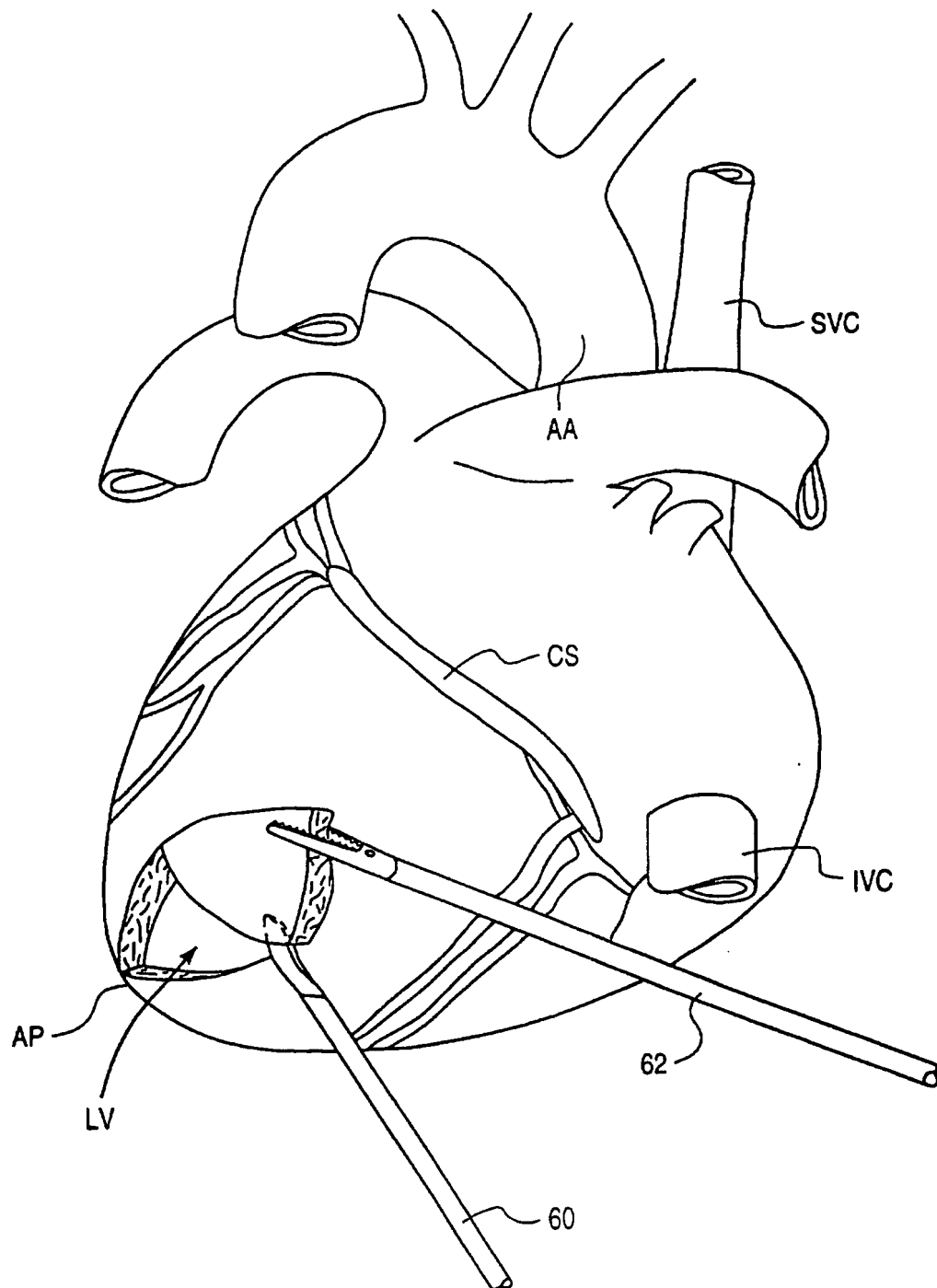


FIG. 3

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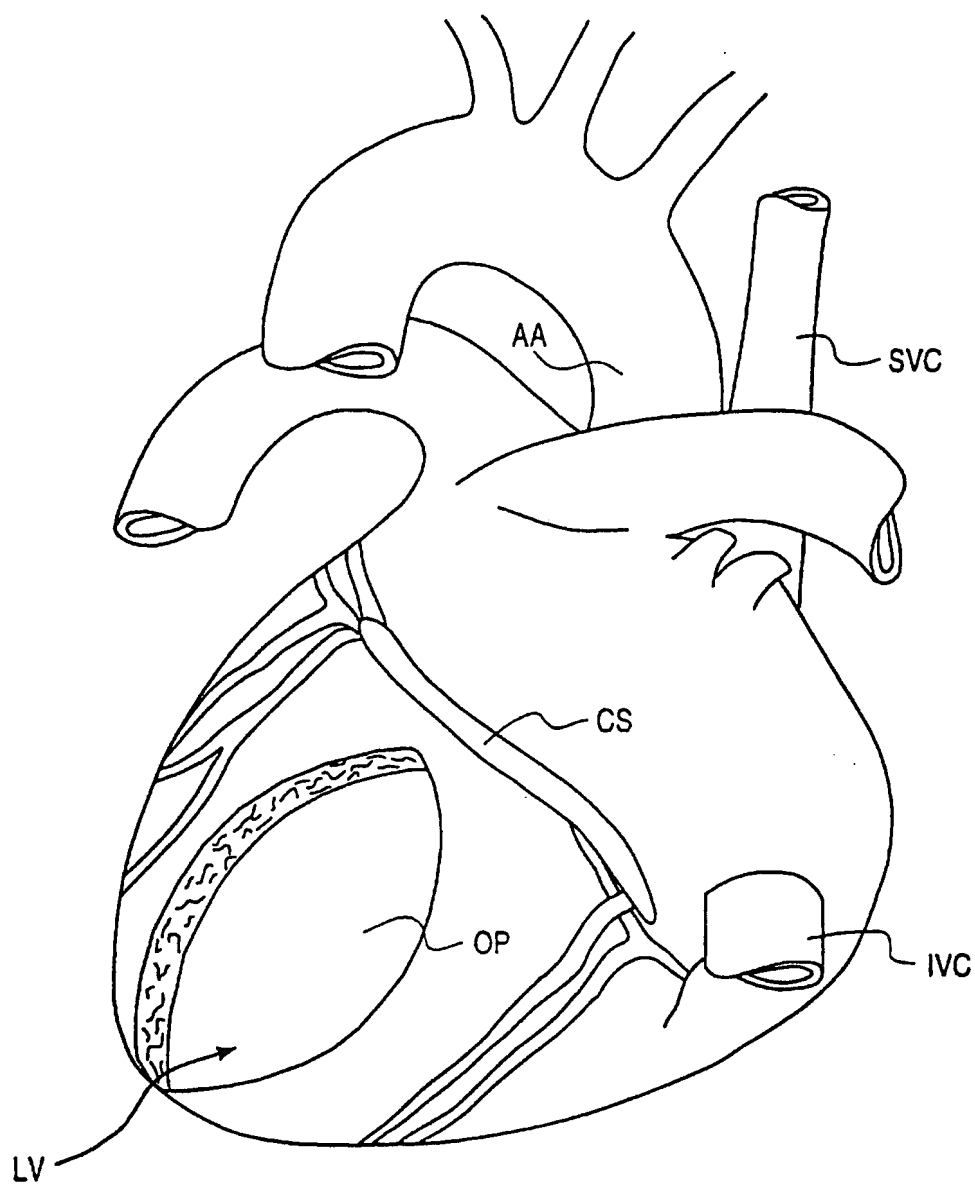


FIG. 4

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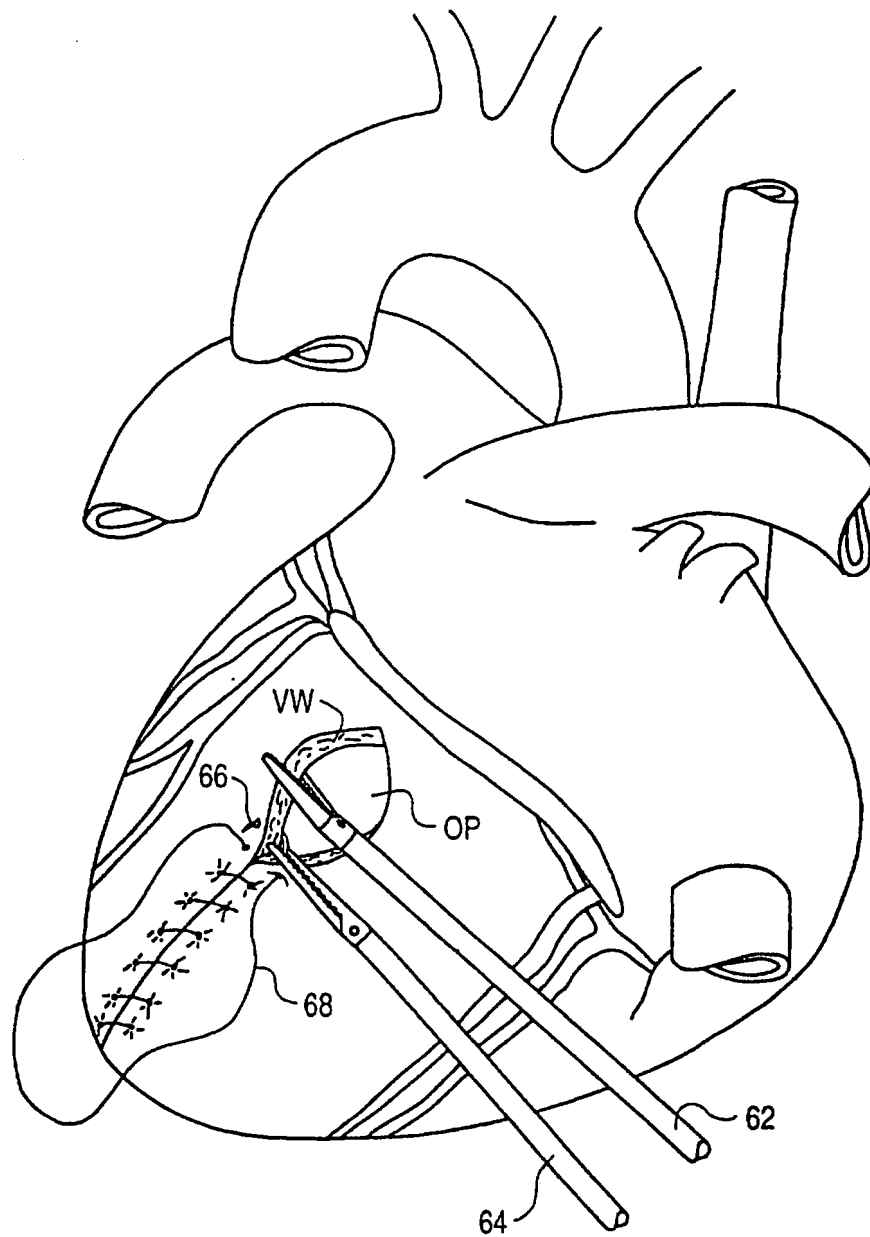


FIG. 5

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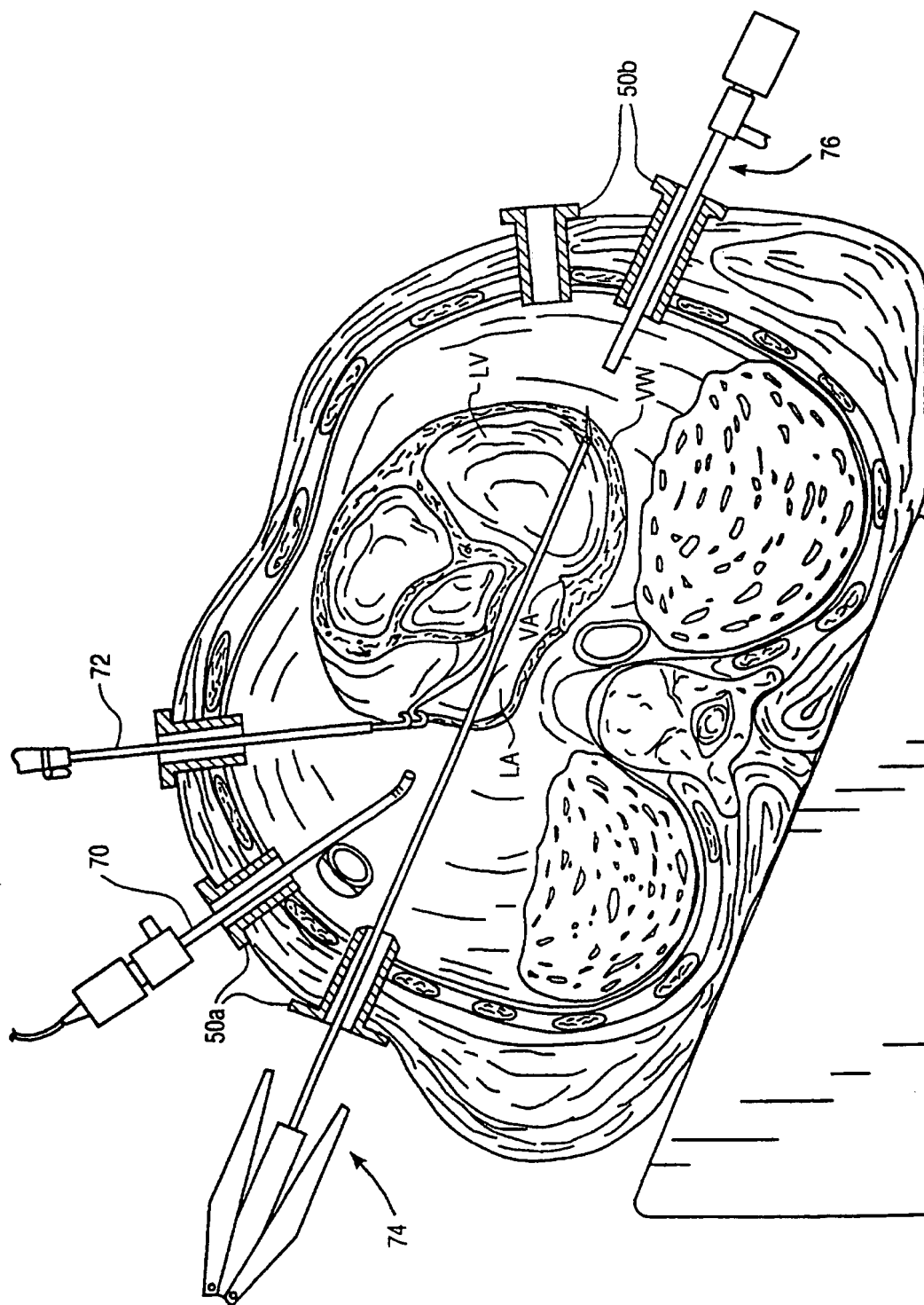


FIG. 6A

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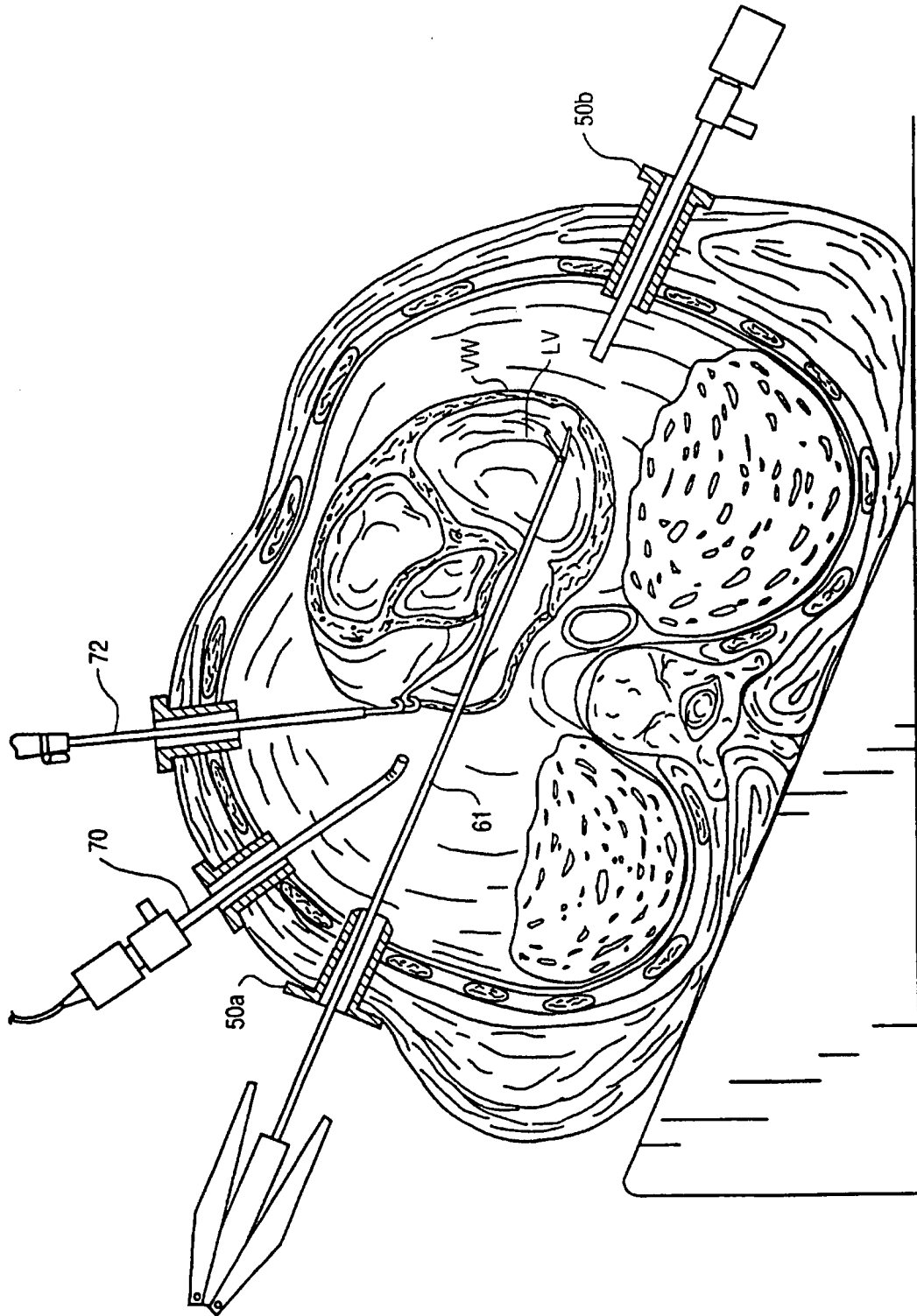
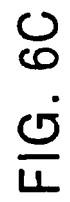
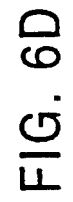


FIG. 6B



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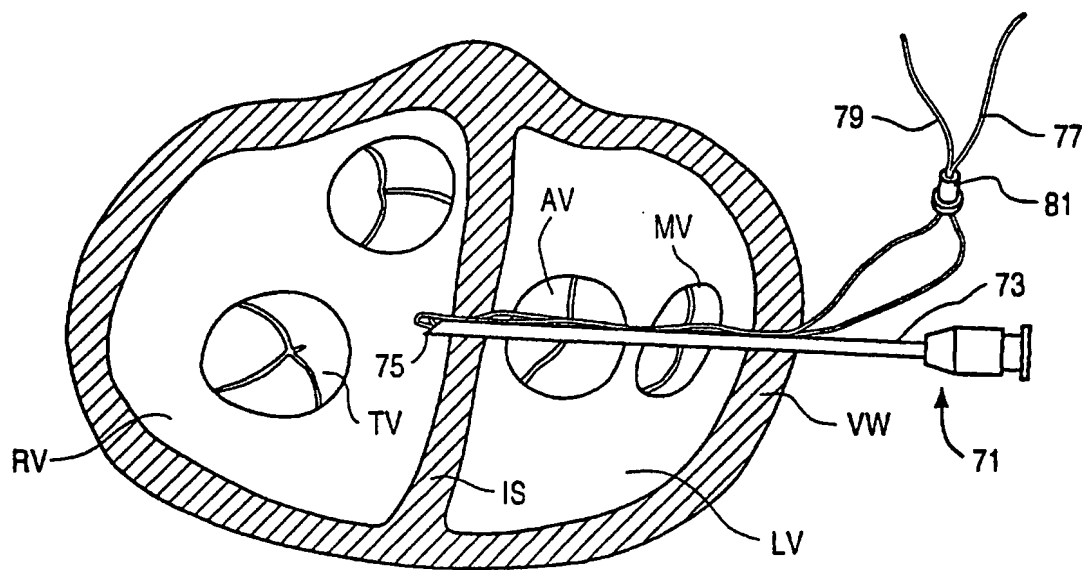


FIG. 7A

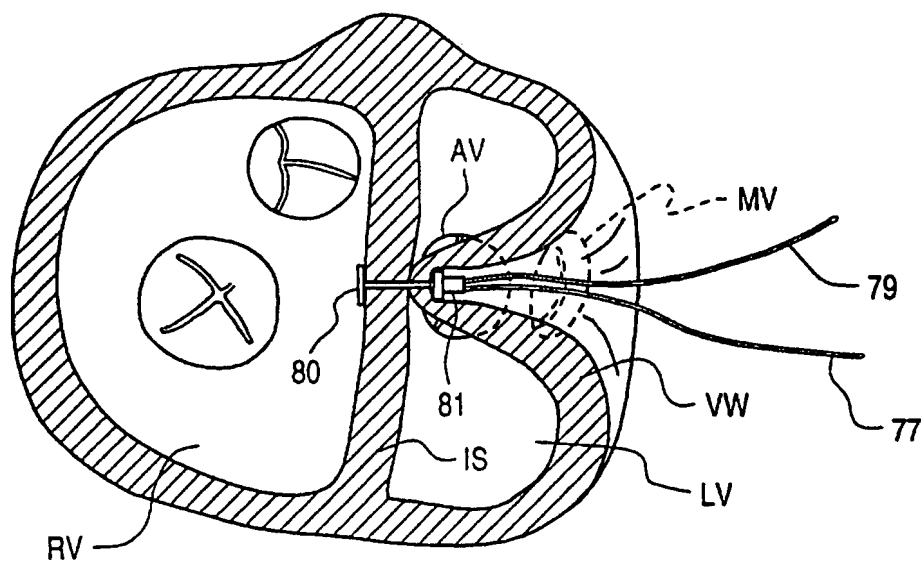


FIG. 7B



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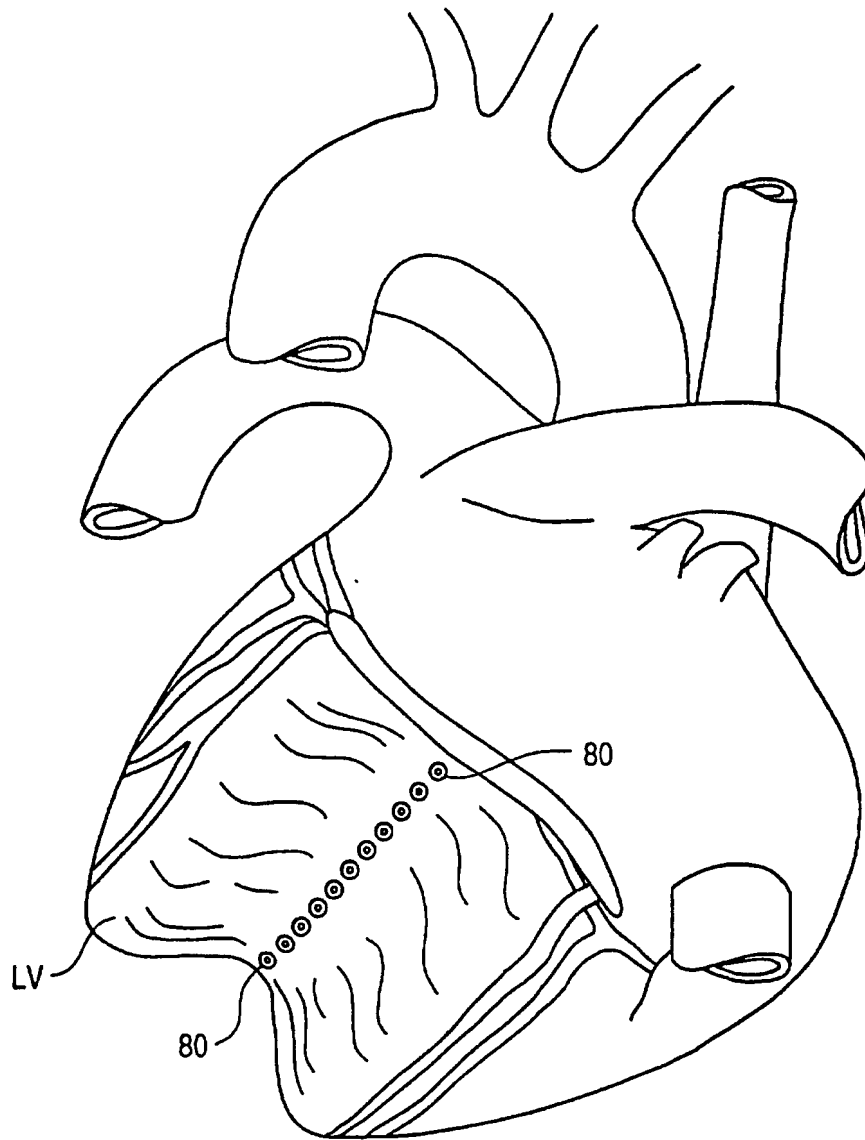
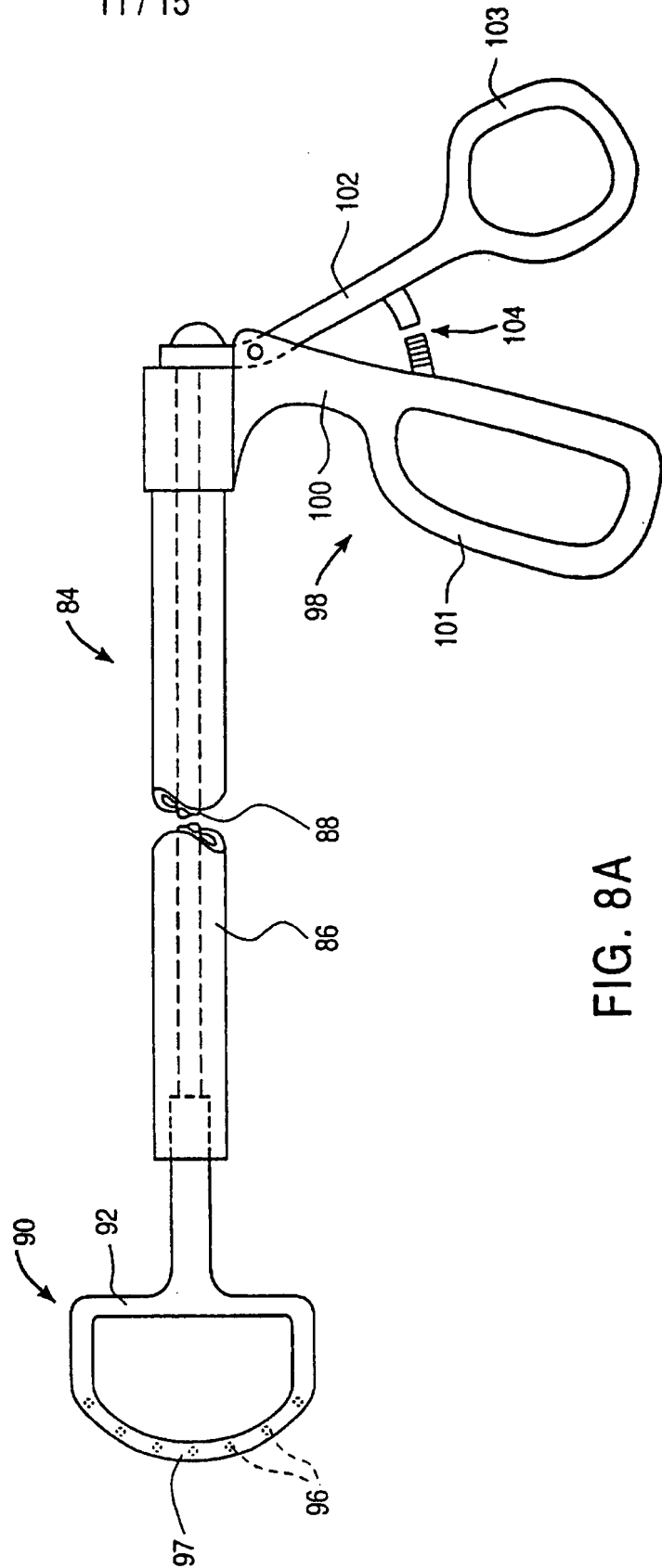
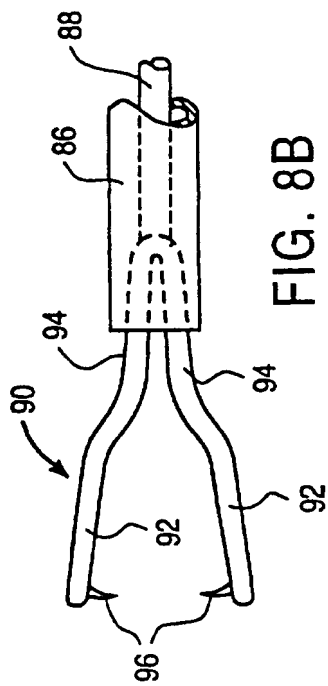


FIG. 7C

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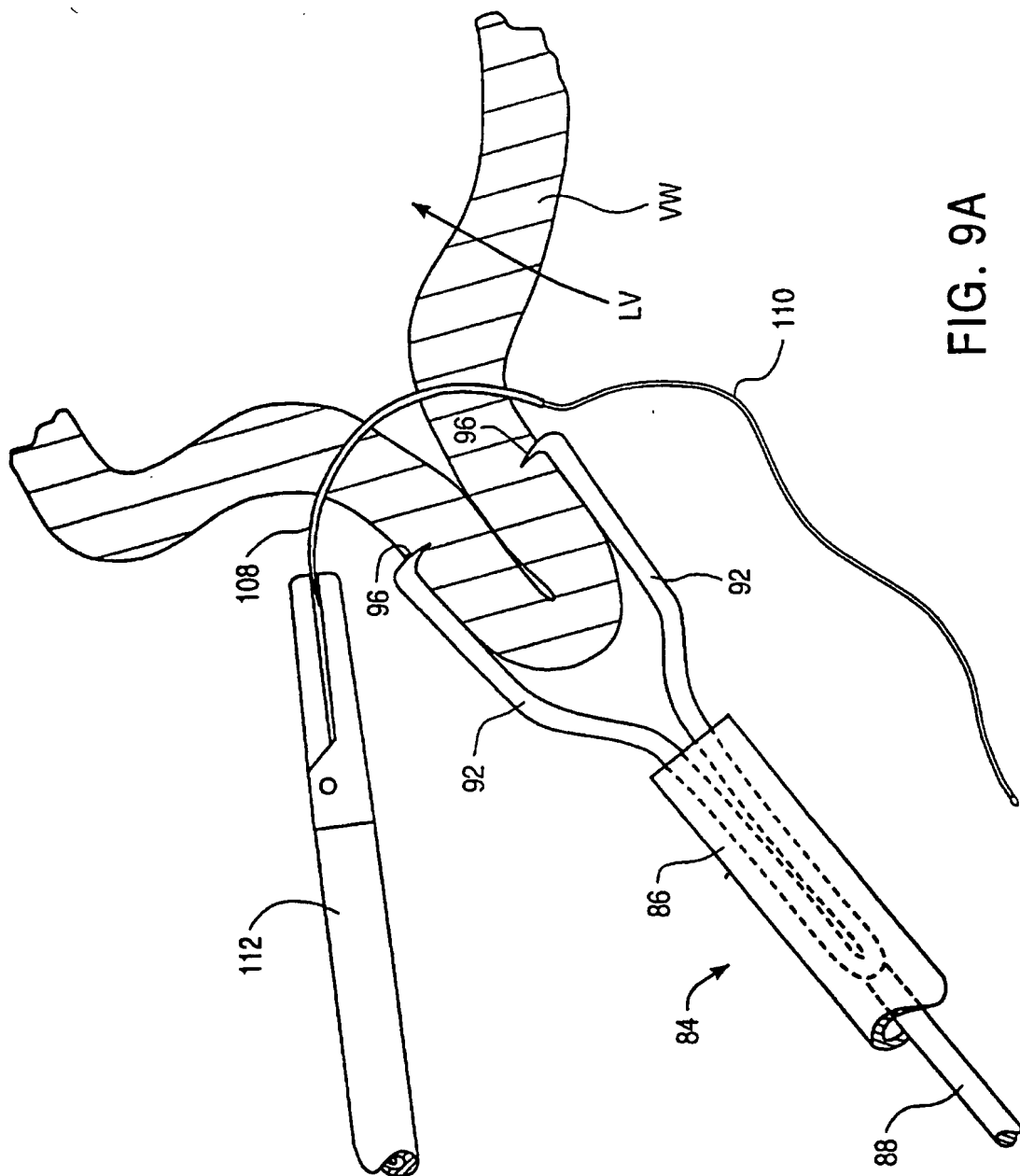


FIG. 9A

13/15

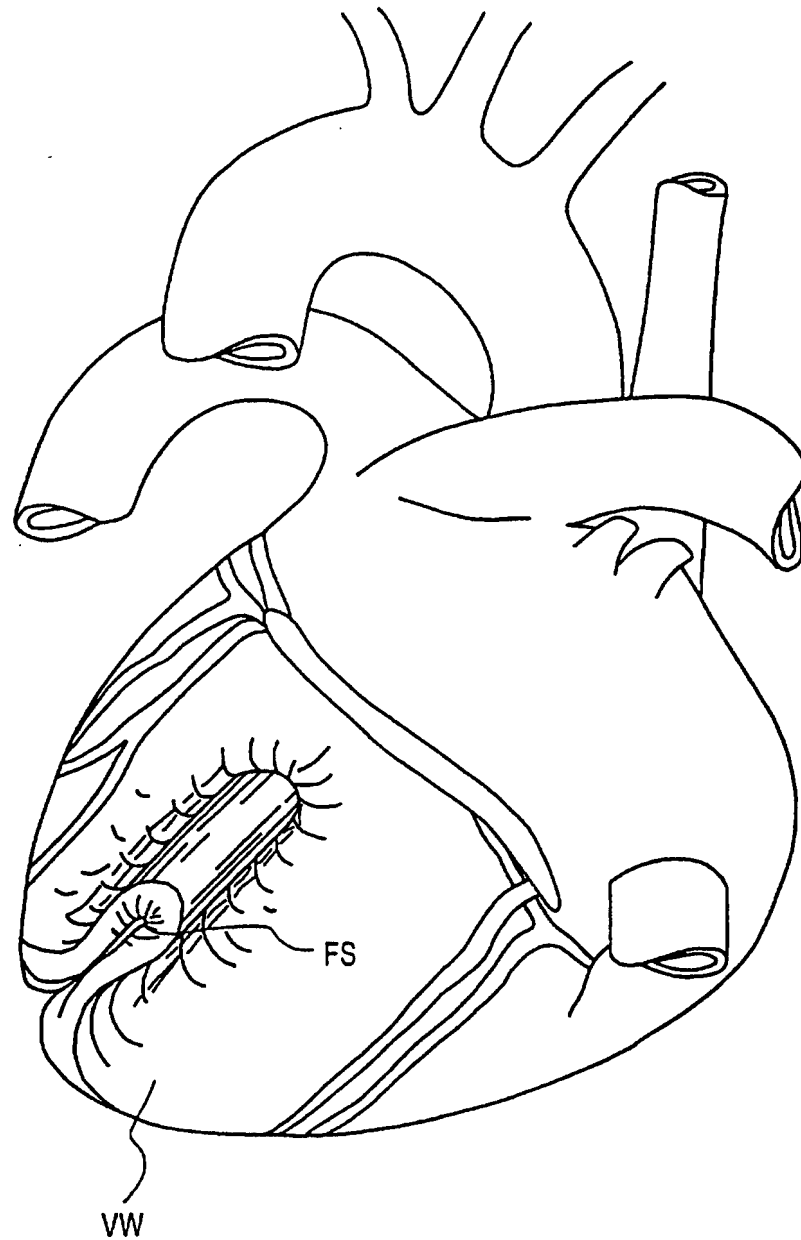


FIG. 9B

14/15

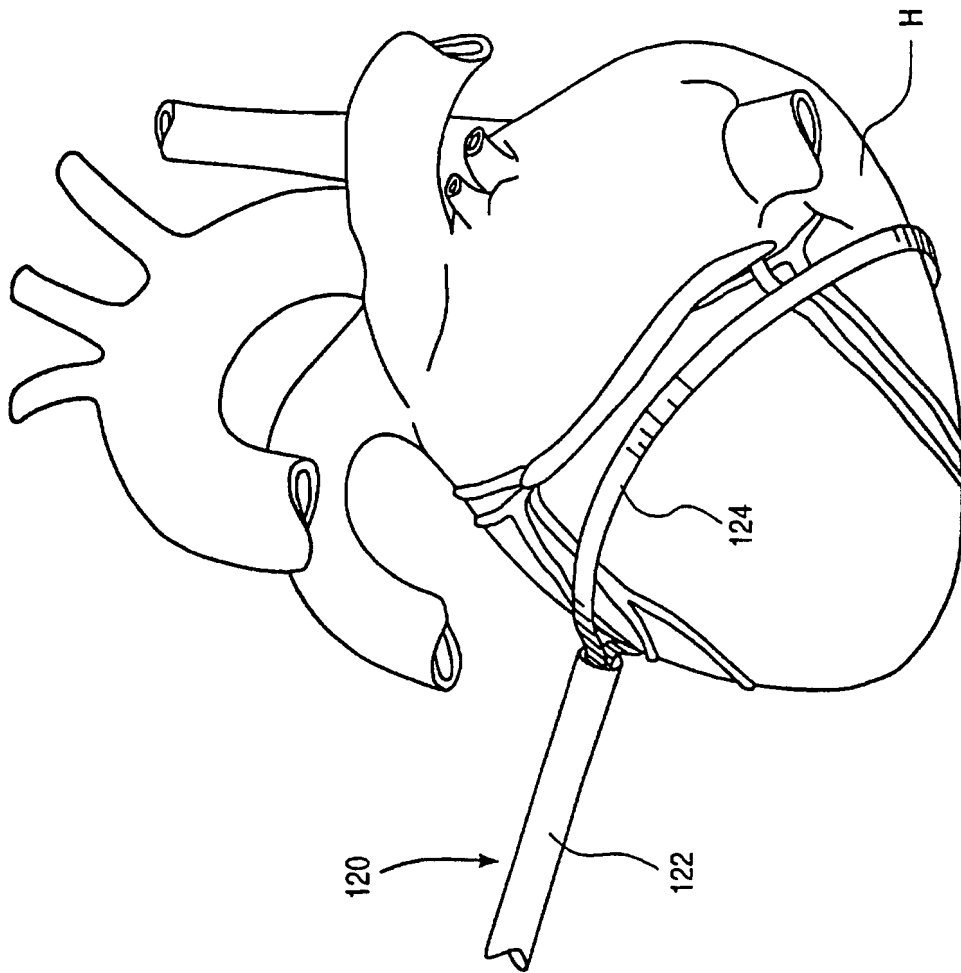


FIG. 10

15 / 15

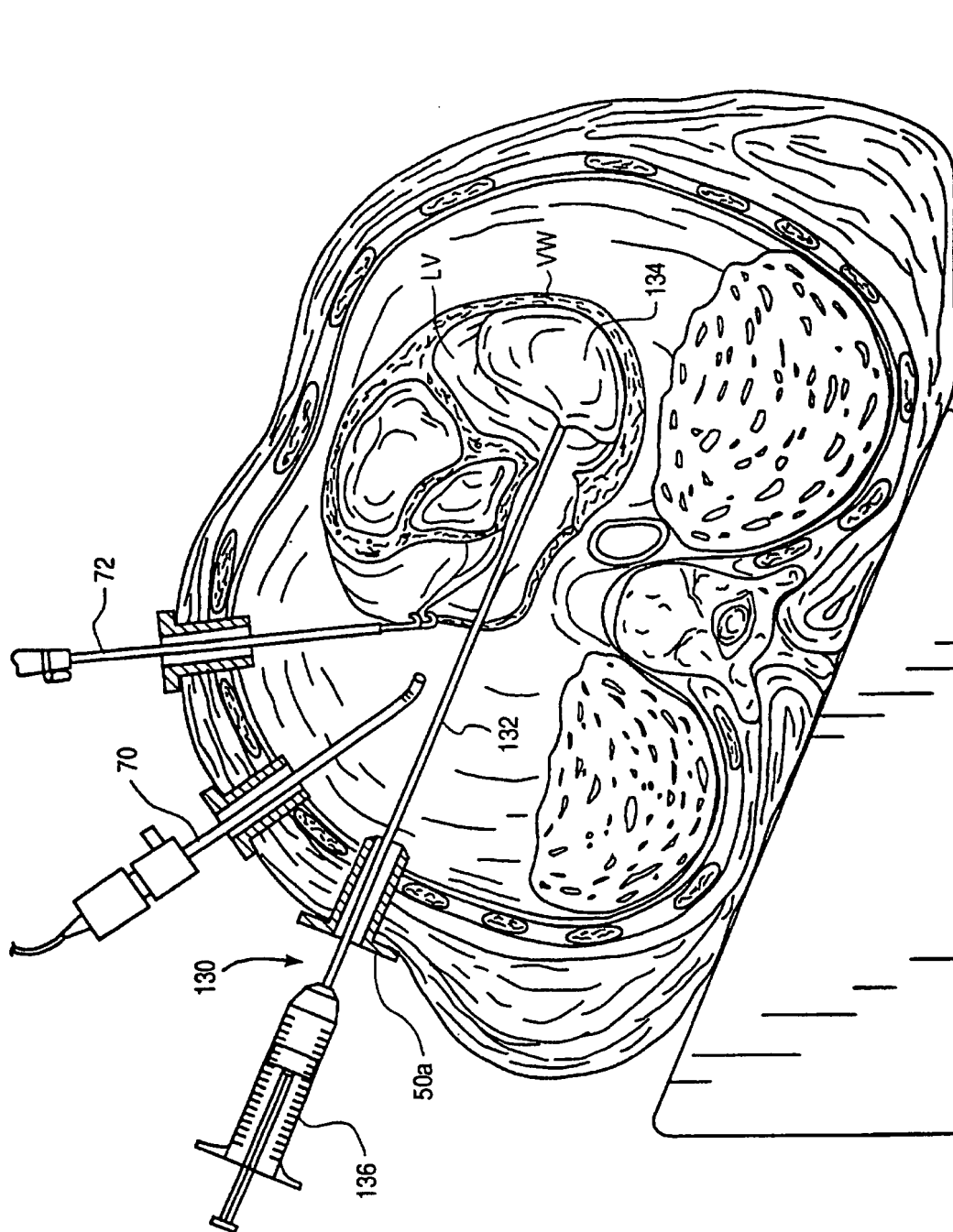


FIG. 11

## INTERNATIONAL SEARCH REPORT

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<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(6) : A61M 1/14 US CL : 604/4 According to International Patent Classification (IPC) or to both national classification and IPC																							
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) U.S. : 604/4 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)																							
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>																							
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.																					
A	US 5,308,320 A (SAFAR et al) 03 May 1994, entire document.	1-14																					
A,P	BATISTA et al, Partial Left Ventriculectomy to Improve Left Ventricular Function in End-Stage Heart Disease, Journal of Cardiac Surgery, November 1996, pages 96-98.	1-14																					
A	OZUNER et al, CREATION OF A PERICARDIAL WINDOW USING THORACOSCOPIC TECHNIQUES", SURGERY. Gynecology & Obstetrics, July 1992, Volume 175, pages 69-71.	1-14																					
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.																							
<table border="0"> <tr> <td>* Special categories of cited documents:</td> <td>* T</td> <td>later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principles or theory underlying the invention</td> </tr> <tr> <td>* A</td> <td>document defining the general state of the art which is not considered to be of particular relevance</td> <td>* X</td> </tr> <tr> <td>* E</td> <td>earlier document published on or after the international filing date</td> <td>document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>* L</td> <td>document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>* Y</td> </tr> <tr> <td>* U</td> <td>document referring to an oral disclosure, use, exhibition or other means</td> <td>document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>* P</td> <td>document published prior to the international filing date but later than the priority date claimed</td> <td>* &amp;</td> </tr> <tr> <td></td> <td></td> <td>document member of the same patent family</td> </tr> </table>			* Special categories of cited documents:	* T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principles or theory underlying the invention	* A	document defining the general state of the art which is not considered to be of particular relevance	* X	* E	earlier document published on or after the international filing date	document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	* L	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	* Y	* U	document referring to an oral disclosure, use, exhibition or other means	document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	* P	document published prior to the international filing date but later than the priority date claimed	* &			document member of the same patent family
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Date of the actual completion of the international search 06 NOVEMBER 1997		Date of mailing of the international search report 28 NOV 1997																					
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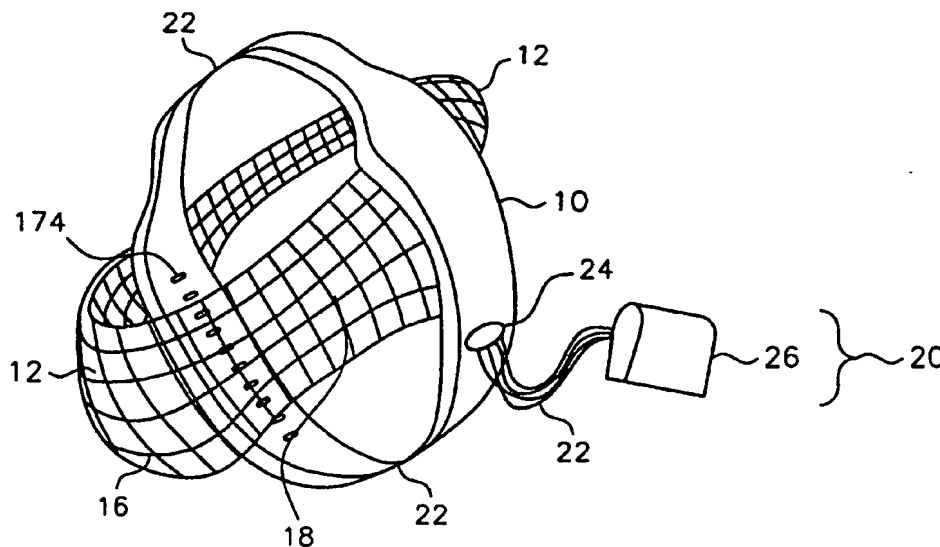
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[Continued on next page]

(54) Title: DEVICES AND METHODS FOR ASSISTING NATURAL HEART FUNCTION



(57) Abstract: Devices and methods for treating a diseased heart including devices and methods for remodeling or reconfiguring a shape of a diseased heart, assisting in function of a diseased heart, and stabilizing such devices on a diseased heart. In some embodiments, the devices and methods include one or more segments for changing a shape of the heart or a portion thereof, and methods for using such devices and methods.



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## DEVICES AND METHODS FOR ASSISTING NATURAL HEART FUNCTION

### FIELD OF THE INVENTION

This invention relates to devices and methods for assisting in the activation and operation of a living heart, including structures for mechanically deforming cardiac tissue such that the circulation of blood is maintained and assisting in movement of cardiac tissue during the cardiac cycle.

### BACKGROUND OF THE INVENTION

Various methods and devices have been proposed for altering the shape of a diseased heart chamber. None have yet proven practical and effective. The present invention addresses a number of new methods and devices to improve, or avoid the deficiencies of prior methods and devices.

### SUMMARY OF THE INVENTION

The present invention is directed to devices and methods for reconfiguring one or more chambers of a natural heart to reduce wall tension on the natural heart walls and/or for reconfiguring one or more structures such as valves, muscles, tendons or other structures of the natural heart, and/or to alter, improve or correct the anatomical structure of the natural heart so that the natural heart can function more efficiently or to correct other problems of the heart. In several embodiments, the segment or segments are adapted to lie adjacent the external surface of the natural heart in an unrestrained position, to cause an inward displacement of one or more locations of the external surface of the natural heart, and to prevent the natural heart from returning to the unrestrained position. In other embodiments, the segment or segments are internal to one or more chambers of the natural heart.

In one or more embodiments, the devices include one or more main segments that encircle a portion of or the entire natural heart at a selected location. The segments of the present invention are configured to provide differential pressure along a selected location of one or more chambers on the surface of the natural heart or a portion thereof by including rigid, semi-rigid and flexible segments or portions thereof, at different locations of the segment or segments of the devices on the natural heart, thereby displacing one or more chambers of the natural heart or a structure thereof (such as a heart valve, muscle, or tendon) and to prevent it from returning to its unrestrained configuration. Several elements such as the main segments or stabilizer/reconfiguration segments can be interchanged and combined with one another to form a

- 2 -

device according to the present invention whereby these segments displace one or more positions of the natural heart and prevent the natural heart from returning to an unrestrained position.

The length and/or configuration of the devices or elements thereof according to the present invention can be adjusted by one or more adjustment and/or closure or locking  
5 mechanisms. Such adjustment and closure features include cables, chains, belts, straps, ratchets, blocks, telescoping elements, expandable elements such as a bellows, or screw mechanisms or similar mechanical or electromechanical devices, combined with or integral to the devices, and that allow adjustment of the devices or portions thereof according to the present invention during initial placement of the devices, and periodically after the devices have already been in place.

10 The devices according to the present invention can be stabilized and/or anchored in position with non-absorbable, partially absorbable, or fully absorbable protrusions; by rigid, semi-rigid or flexible strapping, tabs or curved portions of the segment; by reusable fasteners such as Velcro® or Velcro®-type fasteners; or by the shape or porosity of the segment itself. Stabilization features are adjustable during initial placement of the devices and periodically  
15 subsequent to placement of the devices.

The present invention also includes devices that assist the natural heart to function during one or more portions of the systolic and diastolic cycles. For example, the present invention includes a spring or spring-like mechanism that assist systolic and/or diastolic functions by exerting an outward or inward force on the inside or outside walls of the natural heart.

20 The present invention also includes methods for placing heart reconfiguration devices internal to the heart.

One or more of the devices or elements of specific embodiments shown and described herein can be used alone or in combination with other devices or elements thereof, and other devices not shown herein.

25 The present invention also provides devices and methods for treating cardiomyopathies that address and overcome the above-mentioned problems and shortcomings in the thoracic medicine art. The present invention also provides devices and methods for treating cardiomyopathies that minimize damage to the coronary circulatory, endocardium, and internal heart structures; devices and methods for treating cardiomyopathies that maintain the stroke  
30 volume of the heart; and devices and methods for treating cardiomyopathies that support and maintain the competence of the heart valves so that the heart valves can function as intended.

The present invention also provides devices and methods that increase the pumping

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effectiveness of the heart, and devices and methods for treating cardiomyopathies on a long term basis.

In one embodiment, the present invention provides devices and methods for treating cardiomyopathies that do not require removal of any portion of an existing natural heart. In  
5 another embodiment, the present invention provides devices and methods for treating dilated cardiomyopathies that directly reduce the effective radius of a chamber of a heart in systole as well as in diastole.

The devices of the present invention can be fixed to the heart in a manner which keeps the device in a desired location. In one or more embodiments, the present invention includes a  
10 stabilization system which employs rigid, semi-rigid, flexible belts or straps or harnesses. In one embodiment, the stabilization system or remodeling elements provide a site onto which cardiac transceivers or pacing leads may be secured which allows adding a plurality of transceivers or pacing leads to the heart at whatever spacing and arrangement may be desired.

#### BRIEF DESCRIPTION OF THE DRAWINGS

15 Fig. 1A is a top cross-sectional view of a convex main segment on a heart;

Fig. 1B is a top cross-sectional view of a flat main segment on a heart;

Fig. 1C is a top cross-sectional view of a concave main segment on a heart;

Fig. 1D is a perspective view of a convex main segment on a heart;

Fig. 1E is a perspective view of a flat main segment on a heart;

20 Fig. 1F is a perspective view of a concave main segment on a heart;

Fig. 2A is a perspective view of a heart remodeling clasp including two main segments and apical and atrial segments, in an open configuration;

Fig. 2B is a perspective view of a heart remodeling clasp including two main segments and apical and atrial segments, in a closed configuration;

25 Fig. 3 is a perspective view of a heart remodeling clasp including two main segments and apical and atrial segments, in a closed configuration on a heart;

Fig. 4 is a top perspective view of a heart remodeling clasp including two main segments and apical and atrial segments, in a closed configuration on a heart;

30 Fig. 5A is a side perspective view of a main segment with a stabilizer/reconfiguration segment to support a valvular annulus of a heart;

Fig. 5B is a side perspective view of a main segment with a stabilizer/reconfiguration segment to support the base of one or more papillary muscles;

Fig. 6 is a side cross-section view of a heart fitted with a stabilizer/reconfiguration segment to support a valvular annulus of a heart;

5 Fig. 7 is a perspective view of two adjustable heart stabilizer/reconfiguration segments attached to a main segment;

Fig. 8 is a perspective view of two adjustable heart stabilizer/reconfiguration segments attached to a main segment, on a heart;

10 Fig. 9A is a perspective view of two main segments and atrial and apical segments with pivot points to allow the segments to move with respect to one another;

Fig. 9B is a perspective view of the device of Fig. 9A on a heart;

Fig. 10A is a perspective view of a stabilizer/reconfiguration segment formed of a porous material;

15 Fig. 10B is a perspective view of a stabilizer/reconfiguration segment made of stays, adjustable by cables routed through openings in the stays and the heart stabilizing segments;

Fig. 11A is a perspective view of a stabilizer/reconfiguration segment made of stays, attached to two main segments;

Fig. 11B is a top cross-sectional view of another embodiment of a stabilizer/reconfiguration segment;

20 Fig. 12A is a side perspective view of a heart remodeling clasp including two main segments, an apical segment, an atrial segment and two stabilizer/reconfiguration tabs;

Fig. 12B is a side perspective view of another embodiment of a heart remodeling clasp including two main segments, an apical segment, an atrial segment and two stabilizer/reconfiguration tabs;

25 Fig. 13A is a side perspective view with phantom lines of the device in Fig. 12A;

Fig. 13B is a side perspective view of with phantom lines of the device in Fig. 12B;

Fig. 14A is a side perspective view of the device in Fig. 12A;

Fig. 14B is a side perspective view of the device in Fig. 12B;

Fig. 15A is a side cross-sectional view of a main segment with protrusions on the main segment;

Fig. 15B is a side cross-sectional view of the device in Fig. 15A in contact with heart tissue;

5 Fig. 15C is a top cross-sectional view of a main segment with moveable protrusions on the main segment;

Fig. 15D is a top cross-sectional view of the device in Fig. 15C in contact with heart tissue;

10 Fig. 16 is a perspective view of a main segment with moveable protrusions on a surface of the main segment;

Fig. 17 is a perspective view of a main segment including a multi-segmented, self-orienting plate;

Fig. 18A is a perspective view of an assembled main segment including multi-segmented, self-orienting plates;

15 Fig. 18B is a perspective view of one plate attached to a main segment, with movement of the plate shown by dotted lines;

Fig. 18C is an enlarged perspective view of one plate shown in Fig. 18A;

Fig. 19 is a perspective view of the device in Fig. 18A having a shell;

20 Fig. 20A is a perspective view of an alternative embodiment of a plate of a multi-segmented, self-orienting main segment;

Fig. 20B is a perspective view of multiple plates of Fig. 20A;

Fig. 20C is a perspective view of a main segment including multiple plates in Figs. 20A and 20B;

25 Fig. 21A is a perspective view of another embodiment of a plate of a multi-segmented, self-orienting main segment;

Fig. 21B is a perspective view of a main segment including multiple plates in Fig. 21A;

Fig. 22 is a perspective view of part of a main segment including wire reinforcements;

Fig. 23 is an end view of main segment;

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Fig. 24 is a top perspective view of reinforcement wires of a main segment with a zigzag configuration;

Fig. 25 is a perspective view of a series of reinforcement wires connected by one or more perpendicularly-mounted wire connectors;

5 Fig. 26 is a perspective view of an apical segment;

Fig. 27 is a perspective view of an atrial segment;

Fig. 28 is a perspective view of another embodiment of a main segment;

Fig. 29 is a view of an embodiment of a main segment capable of connecting with adjacent atrial or apical segments by a telescoping open channel joint;

10 Fig. 30 is a view of an embodiment of a main segment capable of connecting with adjacent atrial or apical segments by telescoping complementary interlocking grooves;

Fig. 31 is a perspective view of multiple segment plates or reinforcements of a main segment enclosed in a shell;

15 Fig. 32 is a perspective view of an embodiment of a spring mechanism including a bundle of spring wires linked by tethers;

Fig. 33 is a perspective side cross-section of a ventricle containing two spring mechanisms in Fig. 33, in the ventricle;

Fig. 34 is a side cross-section view of the spring mechanism of Fig. 32, within a ventricle;

20 Fig. 35 is a top cross-section view of two spring mechanisms of Fig. 32 within a ventricle, and two main segments remodeling the ventricle;

Fig. 36 is a top partial cross-section view of two spring mechanisms of Fig. 32 having coatings on the individual wires thereof, before and after tissue overgrowth;

25 Fig. 37A is a side perspective view of an apical coupling cap to be placed over the post tips of two spring mechanisms;

Fig. 37B is side perspective view of Fig. 37A, after placement of the apical coupling cap over the post tips;

Fig. 38 is a perspective view of an insertion sheath containing a spring mechanism of Fig. 32;

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Fig. 39 is a perspective view of the device of Fig. 38 partially inserted into the apical portion of a ventricle;

Fig. 40 is a perspective view of one embodiment of deployment of the spring mechanism from the sheath shown in Fig. 38;

5 Fig. 41 is a top cross-section view of another embodiment of a spring mechanism in a ventricle and connected to two heart remodeling main segments;

Fig. 42 is a top cross-section view of another embodiment of a spring mechanism outside a ventricle and connected to two heart remodeling main segments;

10 Fig. 43 is a side cross-section view of another embodiment of a spring mechanism within a ventricle;

Fig. 44 is a top cross-section view of Fig. 43 and including certain structure of the heart;

Fig. 45 is a side cross-section view of another embodiment of the spring mechanism in a U-shaped configuration in a ventricle;

15 Fig. 46A is a perspective view of positioning of a tether connected to a main segment around a portion of the heart;

Fig. 46B is a side cross-section view of the tether of Fig. 46A surrounding a portion of the heart;

Fig. 47A is a perspective view of the main segment and attached tether in Fig. 46A with the main segment in place on the posterior of the heart;

20 Fig. 47B is a side cross-section view of the main segment and tether on a heart shown in Fig. 47A;

Fig. 48A is a perspective view of two main segments and one or more tethers being placed around a portion of the heart;

25 Fig. 48B is a side cross-section view of the main segments and one or more tethers on a heart shown in Fig. 48A;

Fig. 49A is a perspective view of two main segments and one or more tethers in place on a heart;

Fig. 49B is a side cross-section view of the main segments and one or more tethers on a heart shown in Fig. 49A;



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Fig. 50A is a side view of a spacer between two main segments;

Fig. 50B is a side view of a spacer compressed between two main segments;

Fig. 51A is a side view of a spacer and two main segments with a tether threaded through the spacer and main segments;

5        Figs. 51B-E are additional embodiments of spacers for placement between two main segments;

Fig. 52 is a perspective view of a remodeling device including two main segments, one or more tethers, and an adjustment canister on a heart;

Fig. 53 is a perspective view of the device in Fig. 52 off the heart;

10        Fig. 54A is a side view of another embodiment of a main segment with hinged shoulders (in an open position) and a tether running through the main segment;

Fig. 54B is a side view of the main segment in Fig. 54A with the hinges of the main segment in a closed position;

15        Fig. 54C is a partial perspective view of the main segment in Fig. 54A having slightly wider elements and with the hinges in an open position;

Fig. 54D is a partial perspective view of the device in Fig. 54C with the hinges in a closed position;

Fig. 55 is a perspective view of an embodiment of the present invention including a main segment, a shoulder segments, and adjustable closures;

20        Fig. 56 is a top view of an stabilizer/reconfiguration segment;

Fig. 57A is a perspective view of a clip used to fasten a stabilizer/reconfiguration segment on the device of Fig. 55;

Fig. 57B is a side view of a clip of Fig. 57A;

Fig. 58 is a top view of another embodiment of a stabilizer/reconfiguration segment;

25        Fig. 59A is a perspective view of another embodiment of type of clip used to fasten an stabilizer/reconfiguration segment on the device of Fig. 55;

Fig. 59B is a side view of the clip in Fig. 59A;

Fig. 59C is a top view of the clip in Fig. 59A;

Figs. 60A are perspective and top, respectively, views of a pin used to secure a clip to a stabilizer/reconfiguration segment;

Fig. 61 is a partial perspective view of the device in Fig. 55;

Fig. 62 is a partial perspective view of the device in Fig. 55;

5        Fig. 63A is a top perspective view of the device of Fig. 55 including two main segments with pads attached thereto and the stabilizer/reconfiguration segments in Figs. 56 and 58 attached thereto;

Fig. 63B is side perspective view of the device shown in Fig. 63A;

10        Fig. 64A is a side view of a device in Fig. 55 including two main segments having multi-segmented plates thereon;

Fig. 64B is a perspective view of the device in Fig. 64A;

Fig. 65 is a top cross-sectional view of multiple positions of main segments on a heart;

Fig. 66 is a top view of the device in Fig. 65 placed on a heart and including two stabilizer/reconfiguration segments;

15        Fig. 67 is a side view of a main segment and a stabilizer/reconfiguration segment on a heart;

Fig. 68 is a perspective view of a U-shaped remodeling device including multiple stabilizer/reconfiguration segments and pacing leads;

Fig. 69A is a cross-sectional view of a main segment encased in a suturable material;

20        Fig. 69B is a cross-sectional view of a main segment encased in a suturable material;

Fig. 70 is a perspective view of the device in Fig. 69 A and having one large stabilizer/reconfiguration segment and pacing leads;

Fig. 71 is a perspective view of the device in Fig. 69 and having multiple relatively narrow stabilizer/reconfiguration segments and pacing leads;

25        Fig. 72 is a cross-sectional view of a ball snap clamping mechanism used to attach a stabilizer/reconfiguration segment to a main segment;

Fig. 73A is a cross-section view of placing an umbrella-like anchored tensioning device in a catheter in a ventricle;

Fig. 73B is a cross-section view of the insertion of the anchored device in Fig. 73A;

Fig. 74A is a cross-section view of an anchored tension device in a ventricle with tensioning cords;

Fig. 74B is a cross-section view of the device of Fig. 74A in place;

Fig. 75A is the device in Fig. 73A, including a clamshell like anchor before placement;

5 Fig. 75B is the device in Fig. 73B, including a clamshell like anchor after placement;

Figs. 76A-C are side views of a main segment and stabilization protrusions before, during, and after, respectively, placement of the device on a heart wall

Figs. 77A-C are side cross-section views of a main segment having absorbable stabilization protrusions including a non-resorbable insert, before, during and after, respectively,  
10 absorption of the protrusion on a heart wall;

Figs. 78A-B are side cross-section views of a main segment including tensions stabilization protrusions before and after, respectively, deployment of the protrusions;

Figs. 79A-B are side cross-section views of a main segments including multiple longitudinally aligned stabilization protrusions;

15 Figs. 79C-D are side cross-section views of a main segment including multiple transversely aligned stabilization protrusions;

Figs. 80A-B are perspective and cross-section views of another embodiment of stabilization protrusions

20 Fig. 81A is a side view of the stabilization protrusion of Figs. 80A-B, being placed in a main segment;

Fig. 81B is a side cross-section of the stabilization protrusion in Fig. 81A, in a main segment in Fig. 81A placed on a heart wall;

Figs. 82A-B are side cross-section views of the device in Fig. 81B during and after, respectively, absorption of a portion of the stabilization protrusion;

25 Fig. 83 is a perspective view of a flexible sheath for covering one or more segments of heart remodeling devices of the present invention;

Fig. 84A is a perspective view of the flexible sheath in Fig. 83 in position around a heart;

Fig. 84B is a side cross-section view of the flexible sheath in position in Fig. 84A;

Figs. 85A-85D are perspective views of rigid segments to be placed in the sheath in Fig. 83 to form a heart remodeling device;

Figs. 86A-D are side cross-section views of placing multiple interlocking segments in the sheath in Fig. 83;

5           Fig. 86E is a side view of interlocking rigid segments in Figs. 86A-D;

Fig. 86F is a cross-section view of the device in Fig. 86D and having a final segment encased in a sheath in place on an end of the device;

Figs. 86G-H are cross-section views before and after, respectively, interlocking the final segment in Fig. 86F into place;

10           Fig. 87 is a perspective view of another embodiment of a main segment the curvature of which can be changed;

Fig. 88 is a perspective view of the individual blocks and pins comprising the device in Fig. 87;

Fig. 89 is a side cross-section view of a main segment including the structure in Fig. 87;

15           Fig. 90 is an alternative embodiment of the mechanism in an end block of the device in Fig. 89, for changing the curvature of the main segment;

Figs. 91A-B are a side cross-section views of another embodiment having a single cable for changing the curvature of a main segment, in straight and curved positions, respectively;

20           Figs. 91C-D are side cross-section views of another embodiment having two cables for changing the curvature of a main segment, in straight and curved positions, respectively;

Figs. 92A-B are side cross-section views of another embodiment having one cable for changing the curvature of a main segment including one or more notched edges;

Figs. 93A-B are perspective views of a series of telescoping segments in curved, and in curved and shortened, respectively, positions;

25           Fig. 94 is a perspective view of another embodiment for changing the length of a segment including telescoping elements;

Fig. 95 is a cross-section view of a series of telescoping elements having a slightly longer and narrower configuration;

Fig. 96 is a cross-section view of another embodiment of a segment including telescoping elements, a cable and threaded ends;

Fig. 97 is a perspective view of another embodiment for hydraulically adjusting the length or curvature of a segment;

5 Fig. 98 is a cross-section of another embodiment of changing the length of a segment including telescoping elements and piston bars between the telescoping elements;

Figs. 99A-C are three descriptions of changing the curvature and/or length of segments according to the invention;

10 Fig. 100 is a schematic of placement in a body of an adjustment canister for adjusting the distance of two main segments and/or stabilizer/reconfiguration segments;

Figs. 101A-E are perspective views of a control mechanism including covering caps, push rods and screw assembly, for locally or remotely adjusting the distance between an inside surface and an outside surface of a main segment, or the distance between two opposing main segments,

15 Fig. 102 is a perspective view of another embodiment of an adjustment mechanism for locally or remotely adjusting the distance between an inside surface and an outside surface of a main segment, or the distance between two opposing main segments;

Fig. 103 is a perspective view of another embodiment of an adjustment mechanism for locally or remotely adjusting the distance between an inside surface and an outside surface of a main segment, or the distance between two opposing main segments;

20 Fig. 104 is a perspective view of another embodiment of an adjustment mechanism including a diaphragm and a syringe, for locally or remotely adjusting the distance between an inside surface and an outside surface of a main segment, or the distance between two opposing main segments;

25 Fig. 105A is a side view of another embodiment of an adjustment mechanism including an electric or magnetic drive and a transcutaneous coupling, for locally or remotely adjusting the distance between an inside surface and an outside surface of a main segment, or the distance between two opposing main segments;

30 Fig. 105B is a side view of another embodiment of an adjustment mechanism including a solenoid or permanent magnet driven by a hydraulic pump and a transcutaneous coupling, for locally or remotely adjusting the distance between an inside surface and an outside surface of a main segment, or the distance between two opposing main segments;

Figs. 106A-C are cross-section views of several embodiments of a main segment including an expandable membrane between an inner surface and an outer surface of the main segment, or for moving an inner surface of the main segment relative to an outer surface of the main segment;

5           Fig. 107 is a cross-section views of another embodiment of a main segment including an screw mechanism for moving an inner surface of the main segment relative to an outer surface of the main segment;

Fig. 108 is another embodiment of the device of Fig. 108 including a rotatable cable for advancing the screw;

10           Figs. 109A-B are side cross-section views of a main segment including a lever operated by a pull cord for moving an inner surface of the main segment relative to an outer surface of the main segment, in closed and open positions, respectively;

            Figs. 110A-B are side cross-section views of a main segment including another embodiment of a lever operated by a screw cable for moving an inner surface of the main  
15           segment relative to an outer surface of the main segment, in closed and open positions, respectively;

            Figs. 111A-B are side cross-section views of a main segment including a hydraulic bellows for moving an inner surface of the main segment relative to an outer surface of the main segment, in closed and open positions, respectively;

20           Figs. 112A-B are side cross-section views of a main segment including a hydraulic piston for moving an inner surface of the main segment relative to an outer surface of the main segment, in closed and open positions, respectively;

            Figs. 113A-B are cross-section views of another embodiment of a main segment including an expandable fluid between an inner and outer surface of the main segment, for moving an inner  
25           surface of the main segment relative to an outer surface of the main segment, in closed and open positions, respectively;

            Figs. 114A-B are cross-section views of another embodiment of a main segment including movable screw operated shims between an inner and outer surface of the main segment, for moving an inner surface of the main segment relative to an outer surface of the main segment, in  
30           closed and open positions, respectively;

Fig. 115 is an end view of another embodiment of an apical stabilization cap;

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Fig. 116 is a side view of the device in Fig. 115;

Fig. 117 is a top perspective of the device in Fig. 115;

Fig. 118 is a bottom perspective of the device in Fig. 115;

Fig. 119 is perspective view of another embodiment of an apical stabilization cap;

5 Figs. 120A-B are perspective and side views of an apical stabilization cap including a guide channel;

Figs. 121A-D are perspective and side views of several embodiments of seams of the apical stabilization cap in Fig. 119 or Fig. 120A-B;

Fig. 122 is a side view of the apical stabilization cap in Fig. 119 on a heart;

10 Fig. 123 is partial view in Fig. 122 showing pleats or tucks for circumferential size adjustment of the cap;

Fig. 124 is a perspective view of a main segment stabilized on a heart with an apical stabilization cap;

15 Fig. 125 is a perspective view of a another embodiment of an apical stabilization cap with four circumferential purse strings for adjusting the shape and/or size of the cap;

Fig. 126 is a partial perspective view of two main segments and one or more cables connecting the segments;

Fig. 127 is an enlarged perspective view of a clamping mechanism for clamping cables to the main segment;

20 Fig. 128A is a top view of the clamping mechanism in Fig. 127;

Fig. 128B is a cross-section view of the clamping mechanism in Fig. 127;

Fig. 129 is a top perspective view of a clamp off the main segment;

Fig. 130 is a longitudinal cross-section of the clamp in Fig. 129;

25 Fig. 131 is an enlarged view of a longitudinal cross-section of a portion of the clamp in Fig. 130;

Fig. 132 is a perspective view of a clamping mechanism on a main segment;

Fig. 133 is a cross-sectional view of the center portion of the clamping mechanism in Fig. 132;

Figs. 134-137 are perspective or side views of another embodiment of the a heart remodeling device and a remote adjusting mechanism, including a clamping mechanism;

Fig. 138 is an enlarged side view of a portion of a main segment having three purse string or cable holes;

5 Fig. 139 is an enlarged perspective side view of the clamping mechanism in Fig. 138;

Fig. 140 is an enlarged perspective view of the clamping mechanism shown in Fig. 138;

Figs. 141-142 are side and perspective views of another embodiment of a main segment;

Fig. 143 is an enlarged view of the main segment of Figs. 141-142 on a rigid rod;

10 Fig. 144 is a perspective view of a main segment and a stabilizer/reconfiguration segment on a heart;

Fig. 145 is perspective view of the device in Fig. 144 on a heart with the posterior portion of the device in partial phantom lines;

Fig. 146 is a top view of the base of a heart, with the device in Fig. 145;

15 Fig. 147 is a perspective view of two main segments and two stabilizer/reconfiguration segments attached to the main segments;

Fig. 148 is a top view of the device on the heart shown in Fig. 147 where the heart wall is enlarged below the stabilizer/reconfiguration segments;

Fig. 149A is a perspective view of another embodiment of a stabilizer/reconfiguration segment;

20 Fig. 149B is a perspective view of another embodiment of a stabilizer/reconfiguration segment;

Fig. 150 is a side cross-section view of a heart fitted with a stabilizer/ reconfiguration segment to support a valvular annulus of a heart;

25 Fig. 151 is an enlarged perspective view of a portion of a main segment including a sheath and stabilization protrusions;

Fig. 152 is an enlarged perspective view of another embodiment of a main segment including a covering sheath;

Fig. 153 is a cross-section view of the main segment of Fig. 152 with stabilization protrusions;



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Fig. 154 is a perspective view of two main segments, one or more tethers, stabilization protrusions and a covering sheath over the device;

Fig. 155 is a perspective view of two main segments, one or more tethers, stabilization protrusions and an alternative embodiment of a covering sheath over the device;

5        Fig. 156 is a cross-section view of the main segment in Fig. 155 after placement on a heart wall;

Fig. 157 is a cross-section view of the main segment in Fig. 155 after movement along the direction the arrow;

10       Fig. 158 is a cross-section view of the main segment in Fig. 155 after placement for a period of time allowing tissue ingrowth into the sheath and with secured edges;

Fig. 159 is a perspective view of a dilator body and dilator nose for placing devices according to the present invention;

Fig. 160 is an enlarged view of the dilator body and dilator nose in fig. 159;

15       Fig. 161A-D are perspective and side views of a dilator clasp adapter, for connection to a dilator body and, for example, a main segment;

Fig. 162 is a cross section showing an endoscope surrounding a portion of the heart;

Fig. 163 is an enlarged view through the endoscope in Fig. 162 as it moves to a site of perforation of the pericardium;

20       Fig. 164 is a perspective view of a biting forceps grasping and opening a hole in a portion of the pericardium;

Fig. 165 is a cross-section view a tether or guide wire advanced through a hole in the pericardium, around the heart, and back out through the site of entry, and the endoscope leaving the field of view;

25       Fig. 166 is a cross-section view of a dilator body advanced over a tether or guide wire surrounding a heart;

Fig. 167 is a cross-section view of the dilator body and tether or cable in Fig. 166, and showing a dilator clasp adapter having an end of main segment inserted therein;

Fig. 168 is a cross-section of a dilator body advancing a main segment into position on the posterior portion of the heart;

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Fig. 169 is a cross-section showing one end of second main segment threaded through an end of the tether or guide wire before placement of the second main segment on an anterior portion of the heart;

5 Fig. 170 is a cross-section showing a second end of a tether threaded through a second end of the second main segment before placement of the second main segment on the posterior portion of the heart;

Fig. 171 is cross-section view of the device in Fig. 170 on the heart;

Fig. 172 is a perspective view of a heart with one side of Velcro® fastener having alternating elastic strips, attached to the heart tissue;

10 Fig. 173 is an enlarged perspective view of a main segment with a second side of a of Velcro® fastener having alternating elastic strips attached thereto; and

Fig. 174 is a cross-section of a heart wall and an attached structure (such as a main segment), wherein the structure is attached with a Velcro® fastener having alternating sections of elastic material.

15 DETAILED DESCRIPTION OF THE INVENTION

The invention is described with reference to the drawings. The figures of the drawings are illustrative rather than limiting and are included to facilitate the explanation of the invention.

Remodeling Support Device

20 The invention provides a segment that supports and reconfigures the heart. As shown in Figure 1A, a main segment 10 can be modeled to a heart 1 having actual human cardiac heart failure (CHF) dimensions. Preferably, the main segment 10 is configured and positioned on the heart to provide a contact pressure of about 1.4 to about 0.7 times (+/-0.2) the cavitory pressure.

25 Main segment 10 of the invention can have many differing shapes, depending, for example, on the condition being treated and the size and shape of the heart. The cross section of the segment can have, for example, a convex shape toward the heart (as shown by main segment 10 in Fig. 1A), flat shape (as shown in Fig. 1B as main segment 11), swan shape (as shown in Fig. 12B and 13B), elliptical shape, concave shape (as shown by main segment 12 in Fig. 1C), or a combination thereof. Figs. 1D, 1E, and 1F show main segments 11 of Figs. 1A, 1B, and 1C, respectively, placed on a human heart 1.

30 In addition, main segment 10 can have, for example, an O-shaped configuration such as

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main segment 10 shown in Figs. 2, 2A, 2B, and 4. In Fig. 2A, main segment 10 is shown in an open configuration that is closed to form an O-shaped configuration around the natural heart or a portion thereof, as shown in Figs. 2B, 3, and 4. Main segment 10 can also have adjustment mechanisms for adjusting the size (for example, length and width) and shape (for example, curvature) of the main segment with respect to the heart, including, but not limited to, the adjustment mechanisms shown, for example, in Figs. 53, 55, 62, 87-98. In some embodiments of the devices according to the present invention, up to 30% or more reduction in effective radius (e.g., endocardial or midwall radius) is achieved at initiation of systole.

Referring again to Fig. 4, in one embodiment, the O-shaped device is positioned under the pulmonary artery root into the transverse sinus, then through the pericardial reflection and, respectfully into the oblique sinus between the left and right pulmonary veins. In one embodiment according to Figs. 2A, 3, and 4, and other embodiments of an O-shaped device, spontaneous systolic torsion is permitted by four discrete pivot points located on the device, such as is shown in Fig. 9A as pivot points 10d, as more fully described in U.S. Patent Application No. 09/326,416, which is hereby incorporated by reference. The pivot points may be covered by a tough continuous elastomeric skin.

It is thought that some embodiments according to the present invention work because ventricular wall stress produced by a given intracavitary pressure is altered in direct proportion to the local radius of curvature or, alternatively stated, intracavitary ventricular pressure required to achieve a given wall stress is altered in inverse proportion to the local radius of curvature.

The present invention also provides a stabilizer/reconfiguration segment 12 (as shown for example in Figs. 5A, 5B, 6, 7, 8, and 144-147) that stabilizes main segment 10 on heart 1 and/or supports and reconfigures part of the outside of heart 1 in one or more regions, for example, the region of the mitral or tricuspid valve apparatus in order to improve or eliminate reverse flow through those valves. In one embodiment, the present invention solves regurgitation (also known as insufficiency or incompetence) of the mitral valve or tricuspid valve of the heart. This is a condition in which the leaflets of the valve(s) fail to coapt sufficiently to halt backward flow of blood from a left or right ventricle of the heart to its respective atrium during contraction.

Stabilizer/reconfiguration segment 12 can be either a stand-alone device attached to treat the heart (e.g., valvular disease or separation caused by other heart disease), or used in combination with other heart treatment devices. This device is designed to fit adjacent to and support part of the external surface of the heart for the purpose of aiding mitral or tricuspid closure.

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Preferably, stabilizer/reconfiguration segment 12 can be placed without use of cardiopulmonary bypass, without opening any cardiac chamber, and on a beating heart. Central anchoring of the stabilizer/reconfiguration segment 12 to a ventricular remodeling clasp including main segment 10, or other structure fixed to the ventricular wall, is expected to render the resulting repair more durable, better control valve shape, and be able to have an option of including a step of manipulating papillary muscle base position.

Figs. 5A and 6-11B illustrate stabilizer/reconfiguration segment 12 for stabilizing main segment 10 on heart 1 and/or reconfiguring a portion of heart 1 that supports the valvular annulus of heart 1, directly or indirectly, by fitting around and supporting an outer margin of the junction between the atrium and ventricle, and/or the region thereof, of either the left or right side of the heart. In one embodiment, stabilizer/reconfiguration segment 12 exerts force upon the epicardium of the heart overlying the region of the junction between the left or right atrium and the ipsilateral ventricle (including the contiguous left or right atrial wall, and/or the contiguous left or right ventricular wall, and the coronary arteries and cardiac veins in the region), so that force is transmitted through these structures to the parts of the mitral or tricuspid annulus supporting the mural leaflets (posterior leaflet of the mitral valve and/or both the anterior and posterior leaflet of the tricuspid valve).

Figs. 12A, 12B, 13A, 13B, 14A and 14B illustrate a device including main segment 10 having portions stabilizer/reconfiguration segment 12, 10a, or 10c that supports the base of one or more papillary muscles of either the mitral and/or tricuspid valve. In one embodiment, the device according to the present invention exerts force upon the epicardium overlying the region of the base of the papillary muscles in either ventricle.

It should be appreciated that each of the elements of the invention can be combined to achieve a desired outcome. For example, a structure intended to remodel the mitral valve may be mutually anchored to a structure intended to remodel the tricuspid valve.

Main segment 10 can be open-shaped, such as a ring, band, or collar structure, designed to fit around and support the outer margin of either (i) the junction between the atrium and ventricle and/or a region thereof and/or (ii) a portion of the ventricular wall overlying papillary muscle bases, of either the left or right side of the heart. Main segment 10 can be designed to be connected and supported at either end by attachment to one or more relatively stationary structures.

Main segment 10 can also have one or more portions such as extension segments 10a

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shaped for stabilization and/or support of the main segment 10 adjacent the heart 1, as shown in Figs. 9A and 9B. In one embodiment, extension segment 10a is a tab-shaped, generally curved member, designed to be connected and supported at one end by another relatively stationary structure. Main segment 10 can also include one or more discrete pivot segments, shown in Fig. 5 9A as pivot segments 10d, which can provide low resistance to deformation in a direction perpendicular to the epicardial surface of the heart and can preserve freedom of movement for spontaneous systolic torsion as the heart expands and contracts.

The embodiments shown in Figs. 1A-14B can include one or more adjustable stabilizer/reconfiguration segment 12 to stabilize (e.g., laterally stabilize) main segment 10 adjacent heart 1. One example of this stabilization is shown in Fig. 5A with main segment 10 being stabilized by stabilizer/reconfiguration segment 12. Stabilizer/reconfiguration segment 12 optionally can be shaped, sized, and configured so as to reconfigure the heart or a heart valve. More specifically, stabilizer/reconfiguration segment 12 can be used as shown in Figs. 5A and 5B to cause a reconfiguration (e.g., valve remodeling) of the heart 1. The size, shape, and 15 placement of the stabilizer/reconfiguration segment 12 can be varied depending on intended use. For example, the stabilizer/reconfiguration segment 12 can be used simply as a stabilizing band that passes around the opposite side of the heart (e.g., at least part of the right ventricle and/or atrium in the case of a member supporting the mitral valve) to maintain placement of one or more main segments 10 on the heart.

20 Stabilizer/reconfiguration segment 12 can be formed of numerous materials for stabilizing or supporting main segment 10. In addition, stabilizer/reconfiguration segment 12 can be adjustable as to total length and/or shape, by using, for example, a cord or cable traction, cable torsion, or other means applied directly to stabilizer/reconfiguration segment 12. Furthermore, adjustable stabilizer/reconfiguration segment 12 can be adjusted by means of one or more strings 25 such as purse-strings where stabilizer/reconfiguration segment 12 is totally or partially flexible, or by telescoping of its parts where totally rigid. Such telescoping, in turn, can be driven, for example, by cable tension, hydraulic fluid injection/withdrawal, or turning of threaded members. In addition, stabilizer/reconfiguration segment 12 can be fixed centrally to one or more main segments 10 with sufficient stability to form a cantilever structure by which apically or basally- 30 directed force components of heart-contact pressure serve to stabilize the clasp position in the apico-basal direction.

Main segment 10 and/or stabilizer/reconfiguration segment 12 can also have a heart-contacting surface 27 that is, for example, a solid surface, multiply perforated, such as a net or

mesh (shown for example in Figs. 69a, 69b, 153, 154, and 155), or a combination thereof. In one embodiment, heart contacting surface 27 may be a fluid filled (e.g., gel filled) or 'potting' filled pad, or a surface studded with bumps 28 or beads 29, as shown in Figs. 15A, 15B, 15C, 15D and 16. Figs. 15A, 15B, 15C, 15D, and 16, illustrate a cross section or perspective views of main segment 10 and/or stabilizer/reconfiguration segment 12 having bumps 28. In one embodiment, bumps 28 or beads 29 are roughly hemispheric or semi-hemispheric, fixed projections having a diameter of about 2 to about 2.5 mm, that are spaced about 2 to about 2.5 mm from one another, as shown in Figs. 15A and 15B. Surface 27 may also have, for example, beads 29 that float, i.e., are attached to the surface and are movable with respect to the surface, as shown in Figs. 15C and 15D. Preferably the moveable beads 29 have a diameter of about 1.5 to 2 mm and are tethered about 2.5 to about 3 mm apart. As shown in Figs. 15A, 15B, 15C, and 15D, main segment 10 and/or stabilizer/reconfiguration segment 12 may be brought into contact with a section of natural heart 1 that has a traversing coronary artery 31 near the surface. Artery 31 moves slightly to nestle between beads 29 or bumps 28 due to its own intrinsic mobility. In the embodiment with floating bumps 28 or beads 29, bumps 28 and beads 29 may also move to accommodate positioning of artery 31.

As shown in Fig. 7, the stabilizer/ reconfiguration segment 12 can be formed of a mesh framing 16 having openings 18. Mesh framing 16 is flexible, rigid, or a combination thereof. Factors determining the desired flexibility or rigidity of the stabilizer/reconfiguration segment 12 include valve remodeling, facilitating coaptation of mural and non-mural leaflets, countering displacement of papillary muscle bases, and minimizing cyclic compressive or tensile stress at heart-contacting surfaces. Stabilizer/reconfiguration segment 12 can be made of, for example, a fabric material such as a porous or mesh material.

Stabilizer/reconfiguration segment 12 can also include, as illustrated in Fig. 10B, one or more bars or stays 17 connected to one another via one or more strings or cables 22. Fig. 10A illustrates that in embodiments where stays 17 are not used, adjustment of stabilizer/reconfiguration segment 12 may result in uneven tightening of the drawstrings. In one embodiment, each stay 17 can be identical in size and shape, as shown in Fig. 10B, or one or more of the stays 17 can have different sizes and shapes to optimize stability and/or support, such as stay 17a illustrated in Fig. 11A. Stays 17 can be rigid, semi-rigid, or a combination thereof. In addition, stays 17 can be curved, straight, or a combination thereof, to accommodate the size and shape of the heart.

As shown in Fig. 7, main segment 10 can be positioned and/or stabilized adjacent the

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heart by stabilization protrusions 174, such as pegs, studs, and the like, including the stabilization protrusions described in Figs. 76a-82b.

As shown in Figs. 9A, main segment 10 can also include an extension segment 10a having an end 10b for attachment of a stabilizer/reconfiguration segment 12. End 10b can be  
5 removably connected to one or more means for positioning and/or stabilizing main segment 10 adjacent heart 1.

Stabilizer/reconfiguration segment 12 can also be adjusted to control position, stability, and/or support of the device, as shown in Figs. 7, 10A, and 10B. Fig. 7 illustrates one embodiment of an adjustment mechanism 20 for adjusting and/or maintaining a desired shape  
10 and/or positioning of the main segment 10 and/or stabilizer/reconfiguration segment 12. Adjustment mechanism 20 shown in Fig. 7 includes a string/cable 22 which extends through main segment 10 and or through stabilizer/reconfiguration segment 12 as shown in Fig. 8. String/cable 22 extends out of the main segment 10 at an opening 24 and into an adjustment control mechanism 26 that adjusts the length of string/cable 22, thereby altering the position and/or size  
15 of stabilizer/reconfiguration segment 12 during or subsequent to placement.

Fig. 10B illustrates a stabilizer/reconfiguration segment 12 that is formed of stays 17 connected via string/cable 22 to main segment 10. As shown in Figs. 11A and 11B, stabilizer/reconfiguration segment 12 can include one or more guides 25 extending through openings 23 of stays 17 and through main segment 10 as shown in Fig. 11B.

As shown in Figs. 12A, 12B, 13A, 13B, 14A and 14B, main segment 10 can also be  
20 sized and shaped to support the base or other portions of one or more papillary muscles of either the mitral and/or tricuspid valve of heart 1. Main segment 10 can include, for example, a segment 10c for papillary support, integral with main segment 10, for supporting the base or other portions of one or more papillary muscles.

Embodiments of the stabilizer/reconfiguration segment 12 include:

(1) a totally flexible band or cord, approximately 'C' shaped, contoured to fit the outer surface of the left or right atrioventricular groove, that is fixed anteriorly and posteriorly to the members of an extracardiac remodeling clasp, as shown in Figs. 7 and 8;

(2) a band or cord such as described in (1) above that has an extension intended to lie  
30 adjacent at least part of the external surface of the wall or the left and/or right ventricle and/or atrium as shown in Figs. 7 and 8;

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(3) a rigid collar or ring, approximately 'C' shaped, contoured to fit the outer surface of the left or right atrioventricular groove, that is fixed anteriorly and posteriorly to the members of an extracardiac remodeling clasp (Fig. 9);

5 (4) a rigid collar or ring, such as described in (3) above, that has an extension (10b) attachable to a stabilizer/reconfiguration segment 12 intended to lie adjacent at least part of the external surface of the wall or the left and/or right ventricle and/or atrium (Fig. 9);

(5) a ring, approximately 'C' shaped, contoured to fit the outer surface of the left or right atrioventricular groove, that is fixed anteriorly and posteriorly to the members of an extracardiac remodeling clasp including at least one main segment 10, of which some portion(s) is/are  
10 substantially flexible and other portion (s) is/are substantially rigid (as shown in Fig. 9);

(6) a rigid, flexible, or part-rigid, part-flexible ring, band, or collar, such as described in (1-5) above, of which the heart-contacting surface is a conforming cushion made of a fluid (e.g., gel) or 'potting' filled membrane sac;

15 (7) a rigid, flexible, or part-rigid, part-flexible ring, band, or collar, such as described in (1)-(5) above, of which the heart-contacting surface is a conforming cushion made of a soft solid polymer;

(8) a rigid collar or ring, such as described in (1)-(4) above, for which length can be adjusted in one or more dimensions by means of articulating, telescoping members (Figs. 11A and 11B);

20 (9) a collar or ring, such as described in 8 above, for which telescoping members are controlled by traction via a sheathed string or cable (such as string/cable 22 shown in Figs. 11A and 11B);

(10) a flexible cord or band, such as described in (1)-(9) above, for which length can be adjusted by traction on one or more enclosed cords or cables (such as cable 22 shown in FIG. 11A and 11B; in a purse-string fashion in Figs. 10A and 10B);  
25

(11) a cord or band, such as described in (10) above, in which the enclosed cord or cable length is controlled by traction on sheathed extensions of the cord or cable;

(12) a part-rigid, part-flexible ring, such as described in (5) above, for which length may be adjusted by one or more of the mechanisms described in (8-10);

30 (13) a ring, collar, or band, such as described in (1) - (12) above, that is fixed to, and stabilized by, a flexible band that circumscribes at least part of the length of the opposite side of



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the heart (either in addition to or instead of stabilization by and fixation to the members of a heart-remodeling clasp);

(14) a ring, collar, or band, such as described in (1) - (12) above, that is fixed to and mutually stabilized by another ring, collar, or band that circumscribes the atrioventricular groove  
5 on the opposite side of the heart (either in addition to or instead of stabilization by and fixation to the members of a heart-remodeling clasp);

(15) one or more tabs extending to one side of a member of a ventricular remodeling clasp, or other framework on the heart, positioned to exert normal or tangential force on a region of ventricular wall that supports the base of a papillary muscle;

10 (16) an integral part of a ventricular remodeling clasp, or other framework on the heart, positioned to exert normal or tangential force on a region of ventricular wall that supports the base of a papillary muscle;

(17) one or more rigid 'tabs' that extend from or are optionally integral with a framework, such as a heart remodeling clasp, positioned to displace the ventricular wall segment  
15 that includes a papillary muscle base toward the heart base or the cavity (Figs. 9, 12A, 12B, 13A, 13B, 14A, and 14B); and

(18) one or more areas of deviation that extend from a framework, such as a heart remodeling clasp, positioned to displace the ventricular wall segment that includes a papillary muscle base toward the heart base or the cavity (Fig. 12B).

20 Multi-Segmented, Self-Orienting, Heart-Contacting Plates for Heart Geometric Remodeling

In one embodiment, and as illustrated in Fig. 17, the present invention also provides a heart-contacting main segment 10 that can be employed with the devices of the present invention. In one embodiment, main segment 10 includes one or more segment plates 170 that can be  
25 structured and mounted for rotation about the axis of a rigid frame 172. Rigid frame 172 maintains the centerline of plate 170 in the position prescribed to improve cardiac function (whether as part of a passive device, e.g., a restructuring assembly of the type disclosed herein, or an active device, e.g., a wall-actuating assembly disclosed in U.S. Patent No. 5,957,977, incorporated herein by reference. The permitted segmental or local axial rotation by the plates  
30 170 and the balance of forces dictate that the most stable (lowest-energy) rotational position at any location is transverse tangentially to the heart surface. Segment rotation is sufficiently

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independent such that a plate 170 or part of a plate 170 may pivot if such a configuration is needed to maintain local tangent conformity to the surface of the natural heart.

A cross-section of the locally-rigid frame on which plates 170 are mounted can be, at least in part, arcuate or circular, and plates 170 can be mounted on the frame without axial  
5 fixation, such that the plates may rotate. By having very low torsional rigidity in the long axis of plates, different areas of plates 170 may rotate independent of each other. One advantage is that transverse (meaning perpendicular to the local long axis of the mounting frame) orientation of plates 170 adapts, because of the balance of moments imposed by reaction of the heart surface, to tangency with that surface resulting in substantial or full surface contact.

10 Fig. 17 also illustrates an embodiment of a plate 170, a plate spacer 171, and a frame, shown as rod 172, constructed in accordance with principles of one aspect of the present invention. In one embodiment, plate 170 illustrated in Fig. 17 has a slit or opening 173 adapted to accommodate plate spacer 171. Plate 170 can have any desired shape depending on the particular location of the natural heart or portion thereof to which it is to be applied. In one  
15 embodiment, plate 170 is convex in shape, where the convexity is toward a surface of the natural heart or portion thereof to which plate 170 is applied.

As shown in Fig. 18A, 18B, 18C, one or more segment plates 170 can be positioned on rod 172. Segment plates 170 can include segment plate spacers 171 and can be attached to rod 172, for example, by a snapping action. In one embodiment, plates 170 can be fixedly attached  
20 to rod 172 such that the plates 170 do not pivot or rock with respect to rod 172. In a preferred embodiment, shown in Fig. 18B, plates 170 are removably attached to rod 172 such that plates 170 can pivot or rock and remain tangential with respect to the surface of natural heart 1. It should be appreciated by those of ordinary skill in the art that plate 170 can be attached to the frame by conventional means, such as by a ferrule coupling or pressure fitting, etc.

25 In another embodiment of the present invention, plate 170 can also be partially or fully covered by a shell 190, as illustrated in Fig. 19. The shell 190 serves to protect the patient against infection (e.g., by excluding tissue fluid from poorly-exchanged spaces where it would be a culture medium for bacteria) and also protects the heart surface against erosion by discontinuities between plate components. Preferably, shell 190 is composed of a biocompatible  
30 flexible, low-durometer polymer. In one embodiment, shell 190 includes a gel surrounding plates 170. In another embodiment, shell 190 is a solid shell formed of a uniform polymer material.

Plates 170 also can be formed from one or more plate wires 200, as shown in Figs. 20A,

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20B and 20C. In one embodiment of plate wire 200, illustrated in Fig. 20A, includes a series of single wires. In another embodiment, illustrated in Fig. 20B, plate wire 200 includes a continuous spiraled wire. As shown in Fig. 20C, plate wire 200 can be contained within shell 190.

5           Another embodiment of the heart-contacting plate used to for a main segment 10 according to the present invention is illustrated in Figs. 21A and 21B. As shown in Fig. 21A, the heart-contacting plate can include a rigid or semi rigid plate 210. Plate 210 can include an opening 211 to accommodate the flow of the material forming shell 190 through opening 211 such that the rigid segment plate is embedded within shell 190, as shown in Fig. 21B.

10           Another embodiment of a heart-contacting plate according to the present invention is illustrated in Fig. 22, main segment 10 is formed from individual plate wires 215 embedded in a soft, elastomeric encapsulating material of shell 190. In one embodiment, segment plate wire 215 and shell 190 can have a convex surface that contact the heart, such as that illustrated in Fig. 22. Fig. 22 also illustrates holes 220 which allow the passage of stabilization protrusions 174 such as  
15           pegs shown in Figs. 7, and 76A-82B, through shell 190 into heart 1. This aspect is discussed in more detail below. Fig. 23 illustrates a cross-section of another embodiment of a heart-contacting plate 170 of the present invention in which a plat 170 includes an opening 230 (e.g., a round or oval opening) through which rod 172 can pass.

          Plate wire 200 can also have a flat zigzag configuration, as shown in Fig. 24, prior to  
20           encapsulation in shell 190. In this zigzag configuration, adjacent segment plates wires 200, optionally, can be joined by a bend in the wire at each wire end. In one embodiment, adjacent wire plates 200 are formed from a continuous wire.

          Fig. 25 illustrates an embodiment in which plate wires 200 are connected by one or more plate wire connectors 250. Plate wire connector 250 is preferably mounted substantially  
25           perpendicular to the plate wires 200. Plate wire connector 250 can include, for example, a polymer or wire attached to each plate wire 200, for example, by welding, soldering, or the use of an adhesive. The purpose of wire connector 250 is to facilitate placement of plate wires 200 or similar elements into a mold, and stabilize their position during application or injection of the low durometer polymer or other suitable material to form shell 190.

30           Main segment 10 of the present invention can include a single frame piece or individual components connected together to form main segment 10. In one embodiment, illustrated in Figs. 26-28, main segment 10 comprises an apical segment (270), atrial segment (260), and main

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segment (10), all of which are sized for the particular dimensions of heart 1. Atrial segment 260, as illustrated in Fig. 26, can be configured for placement adjacent the atrial wall. As shown in Fig. 27, apical segment 270 can be configured for placement adjacent the ventricular apical wall. The outer surfaces of atrial and apical segments 260 and 270 shown in Figs. 26 and 27 can be covered by a textured material, such as, for example, a velour, porous (such as a mesh) fabric, to facilitate tissue ingrowth and fixation.

Fig. 28 illustrates an embodiment of a main segment 10 having a central spine 286 that is configured for placement adjacent a portion of the ventricular wall and atrioventricular junction and extensions 281 and 282 that are either straight or arcuate, depending on the shape of heart 1. More specifically, main segment 10 illustrated in Fig. 28 includes extension 281 having a connector portion 287 (such as a hollow section for releasably accommodating atrial segment 260, as shown in Fig. 26) for connection to apical segment 260; a curved section 283 convex to the heart, approximating a circular arc of about 60 to 90 degrees and intended to lie adjacent the atrioventricular junction, preferably having a radius of curvature ranging from about 5 to about 15 mm; a ventricular shoulder section 284 concave toward the heart, having a circular arc, generally having a radius of curvature of about 10 to about 30 mm, and generally extending about 60 to about 90 degrees; a main section 285 that is approximated by a circular arc (for example, having a radius of curvature of about at least about 100 mm or greater) or an elliptical arc (having a major hemi-axis of at least about 100 mm or greater); and a connector 288 (such as a hollow section for releasably accommodating apical segment 270 as shown in Fig. 27) for connection to apical segment 260.

Figs. 29 and 30 illustrate embodiments of extensions 281 and 282 for connection to the atrial segment 270 and apical segment 260, respectively. In a preferred embodiment, extensions 281 and 282 are telescoping and include indexed (e.g., ball and socket or ratchet) or continual sliding adjustment mechanisms. Alternatively, extensions 281 and 282 can be side-by-side interlocking grooves that provide flexural stability. Extensions 281 and 282 may be circular or non-circular in cross-section. Straight extensions are preferred, as the degree of telescoping does not impose any change in the relative angulation of the two ends of the complete rod assembly. If extensions 281 and 282 are curved, the degree of combined (between both atrial segment 260 and main segment 10, and between apical segment 270 and main segment 10) telescoping without unacceptable change of end angulation may be limited.

Generally, closed, non-communicating spaces that would contain stagnant tissue fluid should be avoided. This can be accomplished, for example, by open-sided, outside telescoping

section as shown in Fig. 29, or by one or more fenestrations in the outside telescoping section, as shown in Fig. 30. It should be appreciated that conventional means of position locking after adjustment of the length of rod 172 can be employed, including, but not limited to, set screws and tightening collets (e.g., a metal band, collar, ferrule, or flange).

5           Fig. 31 illustrates main segment 10 including a multiple of plates 170 (not shown), rod 172 and shell 190 forming heart-contacting surface 27 of a pliable and/or elastic material for placement adjacent the ventricle or a portion thereof, the atrio-ventricular junction, and part or all of the atrial wall, preferably the portion of the anterior or posterior atrial wall nearest the atrio-ventricular junction. Plate 170 and rod 172 can be pre-attached, either flexibly or rigidly, or can  
10           be joined at the time of placement of the device. Multiple plates 170 attached to a single rod 172 can be formed according to any of the embodiments shown in Figs. 17-28.

          The present invention also includes an embodiment where a single large plate (e.g., a solid, semi-solid, fluid or 'potting' filled pad) in the shape as shown in Fig. 31, is substituted for a multiple of plates 170. The single large plate or pad is attached to rod 172 and has sufficient  
15           torsional flexibility over its entire length such that the plate can conform to a surface of the natural heart to which it is to be applied and maintain a position substantially tangent to the natural heart surface even while the heart contracts and expands.

          The mounting framework for a heart remodeling device according to the present invention that employs plates 170 or a large single plate, of the present invention is made of a generally  
20           circular or round cross-section rod 172. Rod 172 is curved so that its inner (toward the heart) surface approximates the centerline of intended heart-wall contact. Mounted on this framework are an alternating series of plates 170, alternating with plate spacers 171. Plates 170 are approximately rectangular when viewed from the direction of the heart surface. When viewed from a direction along the local frame axis, the heart-contacting surface is generally a circular  
25           arc, having a radius of about 60 to 200 mm, or an elliptical arc (having a major hemi-axis of at least about 100mm or greater). On the opposite side, viewed from this same direction, there is a notch of a width and shape to accept and snap onto rod 172, after which plate 170 may rotate on rod 172. Spacers 171 are part of a circle, that similarly fit onto rod 172, alternating with plates 170.

30           Plates 170 are generally about 1 to 12 mm in the dimension that parallels the local orientation of the frame. In that same dimension, spacers 171 are generally about 1 to 12 mm. Plates 170 are generally about 12 to 30 mm in the direction that is both perpendicular to the local frame and parallel to the local heart surface, the width intended for the completed frame at that

location. This dimension, as well as the radius of curvature for the plate 170 surface that is to contact the heart, is computed from heart diameter, wall thickness, geometric values, and the intended epicardial to cavitory pressure ratio and extent of intended radius reduction.

5 In the direction that is perpendicular both to the local frame and to the local heart surface, the dimension of rod 172 and plate 170 is sufficient to effect sufficient flexural rigidity across the width of the completed plate 170 to prevent substantial deformation under expected forces when mounted on rod 172 and used to deform the heart as intended clinically. After assembly, the entire plate 170, spacer 171 (if used), rod 172 assembly is covered with a low durometer polymer, that is biocompatible, such as a polyurethane or a silicone rubber, as in Figs. 20c and 10 31.

The present invention reduces or eliminates non-tangential contact between plates of a ventricular geometric remodeling device and the ventricular epicardial surface. Consequences of such non-tangential contact are mediated by excessive pressure, and include local subepicardial tissue ischemia, coronary artery occlusion and/or damage, and possible erosion into the surface. 15 The present invention also reduces or eliminates the attendant risk of excessive localized pressure which may cause on of the above consequences.

Plates 170 are different from standard plates 550 (such as that shown in Fig. 31 or 55 below) that are fixed to the support structure of a remodeling device (such as a heart remodeling device such as the CardioClasp) in that the plates 170, upon contact with the epicardium, rotate to 20 the lowest-energy (most stable) position, preferably tangent to a surface of heart 1.

An advantage of the invention is that the lowest-energy (most stable) position, because of the structure of plate 170 mounting, is tangent with the epicardium, rather than a fixed orientation to the frame of the device, which would risk edge effects and excessive contact pressure between the remodeling device and heart 1.

25 Variations of the invention include:

(A) An assembly similar to that shown in Figs. 19, 20C, 21B, 22 and 31 (all of which may include a low-durometer polymeric filling, 'potting', or fluid such as a gel), may also be used but without the low-durometer polymeric filling, 'potting', or fluid (e.g., a gel).

(B) Plates 170 (such as in Fig. 17) made of a low-durometer polymer, such as a 30 polyurethane or a silicone rubber, that is reinforced by embedded wire, either a multitude of wire loops or links of coiled wire. In one embodiment, the wire reinforcement provides sufficient rigidity of the surface in the direction perpendicular to the long axis of plate 170. Plates 170

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themselves have little torsional rigidity or intrinsic longitudinal rigidity. Longitudinal rigidity is imposed, however, by cylindrical rod 172 onto which plates 170 are mounted. Mounting may be either via a central hole or bore through the long axis of plates 170 or (preferred) a slot in the surface (the 'free surface') opposite that contacting the heart. The width of the slot decreases, at least at intervals, to slightly less than the diameter of rod 172 near the free plate surface so as to allow a 'snapping-on' type of position stability. As is the case with plates 170 (either (A) above or the preferred embodiment described earlier), blunt stabilization protrusions 174 or fixation pegs, if used, would be mounted in or to rod 172 and pass through holes in heart-contacting surface 27 of shell 190.

10 (C) Plates meeting the description of (B) except that the reinforcement plates or wires are multi-perforated, generally 1 to 3 mm thick, mini-segments of rigid biocompatible polymer or metal embedded at intervals in the of the low-durometer polymer shell 190. The mini-segments impose and permit the same range of rigidity as do the wire reinforcements of (B).

#### Systolic to Diastolic Pressure Transfer Mechanism

15 In Figs. 24-45, there are shown a number of embodiments of heart assist and reconfiguration devices including elastic members placed inside or outside the heart and configured to contact a portion of a heart wall to exert a force thereon. As shown, these embodiments generally comprise one or more spring members configured to be positioned adjacent a section of a heart wall and to be biased against the heart wall. This may be  
20 accomplished by various configurations of wire leaf spring members.

Alternatively, this may be accomplished by suitably shaped and heat treated metal such as stainless steel or shape memory metal such as nitinol, forming a suitably configured shell, possibly configured by computerized conformation to the shape of the desired location within or outside the heart, and then laser etching the device from the shell.

25 As shown in Figs. 24-45, these embodiments include a spring mechanism 327 including a fan-like array 323 or a single spring element such as spring 425 in Fig. 42, that exerts outward force against the inside of the left or right ventricle of the heart. Spring mechanism 327 works by storing energy while the ventricular walls move centrally during active contraction of the ventricles (cardiac systole), and releases that energy while the ventricular walls move outward  
30 during passive relaxation of the ventricles (cardiac diastole). By using preferably metallic (such as CP titanium or stainless steel) springs, with low hysteresis or energy loss, relatively little energy is lost. Since the movement of the ventricular walls in contraction and in relaxation is

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equal and opposite, near-equality in energy storage and release means that the pressure effect will be the same. That is, spring mechanism 327 will reduce pressure within the ventricle by a numerically near-equal amount in systole and in diastole, at equivalent ventricular size. The pressure decrement will be the same in early systole as in late diastole, in mid-systole as in mid-diastole, and in late systole as in early diastole. When the wall moves inward with contraction, spring mechanism 373 is also deformed inward. This exerts an outward force on the wall both during contraction and relaxation that is determined principally by the instantaneous ventricular circumference. The relationship between instantaneous circumference and pressure decrement is dependent on the characteristics of spring mechanism 327 such as the effective spring constant if its structure renders it linear in action, its tangent spring constant at each level of deformation otherwise, and its resting configuration. The natural outward force of the ventricle, simultaneous size and shape of the ventricle as well as the spring constant determine the absolute amount of pressure decrement, that is, the difference in chamber pressure from what it would be if the spring mechanism were absent.

Spring mechanism 327 can be used for patients who have symptoms or risks associated with decreased compliance of the ventricles during filling. This is generally manifested by increased pressure in the ventricle(s) at the end of filling (elevated left or right ventricular end-diastolic pressure, LVEDP or RVEDP), which in turn leads to elevated left or right atrial pressure and then to elevated pressure in the veins draining the lungs (pulmonary veins) or the veins draining the body (systemic veins), respectively. Symptoms of a left sided problem include shortness of breath and risks are dangerously low oxygen saturation because of fluid in the lungs (pulmonary congestion, progressing to pulmonary edema). Symptoms of a right sided problems include swelling of the legs and feet, followed by fluid in the abdomen and swelling of abdominal organs, particularly the liver, while risks are poorer blood flow through organs, particularly the liver, and failure of those organs.

Spring mechanism 327 is also suitable to provide a margin of reserve in the strength of contraction of the ventricles such that reduction of the systolic (contracting) pressure in that ventricle or ventricles would be expected to cause lesser problems than those relieved by reducing the diastolic (filling) pressure of that same ventricle.

Accordingly, spring mechanism 327 is useful in, but not limited to, such patients as recipients of a treatment, such as geometric remodeling of a ventricle with or without a specialized device as described herein or in U.S. Patent No. 5,702,343 (Acorn), U.S. Patent No. 6,085,754 (Acorn), U.S. Patent No. 5,961,550 (Myocor) or U.S. Patent No. 5,800,528



(Abiomed), all of which are hereby incorporated by reference, or recipients of a partial left ventriculectomy. One advantage is a well tolerated partial loss of now-excessive systolic pressure reserve in exchange for a significantly beneficial reduction of diastolic filling pressure. These treatments may tend to induce an upward (which would be unfavorable) proportional change in  
5 ventricular filling pressure that is, relative to the basal filling pressure, similar to the favorable proportional upward change in ventricular ejection pressure reserve. However, since baseline ejection pressures are from 4 to 15 times as high as baseline filling pressures, similar arithmetic reduction in each will have a much more significant favorable effect on filling pressure than it does an unfavorable effect on ejection pressure.

10 In one embodiment, spring mechanism 327 includes at least one, preferably two, and possibly more than two, bundles 320 of spring wires 321 that lie against the inner walls of the ventricle, as shown in Fig. 32. Spring wires 321 of each bundle 320 or a plurality of bundles 320 are fixed to each other at one end 322, placed at or near an apical end of the ventricle. From that point, each bundle forms a fan-like spring array 323 with each wire 321 extending toward the  
15 base 340 of the ventricle as shown in Fig. 33, 34, and 37B. Spring wires 321 may, or may not, be individually covered by a porous or textured polymer covering 360 (as shown in Fig. 36), such as expanded polytetrafluorethylene (ePTFE). Similarly, wires 321 of a bundle 320 may be joined by polymer strands or tethers 324.

The set curvature of individual wires 321, and their alignment at the point of joining, is  
20 such that when released, the array of wires 321 in a bundle 320 conforms to part of a hollow solid somewhat larger than the ventricle being remodeled. In the case of the left ventricle, this would be in the general shape of part of an ellipsoid of revolution of minor axis greater than that of the ventricle. Both the resting shape of spring wires 321 and the flexural rigidity of spring wires 321 are selected such that an average outward force is exerted on the ventricle at all points in the  
25 cardiac cycle commensurate with the desired reduction in cavitory pressure. At the point of junction, such as post tip 330 of spring wires 321 of each bundle 320, spring wires 321 coalesce into a solid rod, fabricated by welding or by adhering with a biocompatible adhesive two or more spring wires 321, such as by using an epoxy compound.

The present invention embodied in Figs. 32-45 treats the problem of symptomatic or  
30 hazardous elevation of diastolic pressure in the cardiac ventricle(s). It is different from either vasodilating or diuretic medications in that there is no reason to expect any effects other than on the heart. In addition, there is no direct risk of renal (kidney) damage or dysfunction, of electrolyte imbalance, or of dehydration using the present invention, in contrast to the use of

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diuretic medicines. Furthermore, there is a lesser risk of symptomatic hypotension using the present invention than with the use of vasodilator medicines.

Fig. 32 illustrates one embodiment of the present invention. As shown in this figure, bundles 320 of spring wires 321 can be composed of spring wires 321 having an apical end 322  
5 and linked by interlinking strands or tethers 324.

Fig. 33 illustrates halves of two bundles 320 shown inside and against the wall of a longitudinally sectioned left ventricle 331 (cut perpendicular to septum, viewing toward posterior wall) and having post tips 330.

Fig. 34 illustrates bundle 320 shown as seen from inside a longitudinally sectioned left  
10 ventricle (cut parallel to septum, viewing toward free wall 341), in relation to the apex 342 of the ventricle and base 340 of the ventricle.

Fig. 35 illustrates a top view of a transverse section of a heart in which two bundles 320 have been positioned against the free wall and septum, respectively, of the left ventricle. Fig. 35 illustrates bars or plates 350 of a ventricular remodeling device (as shown, for example, in Figs.  
15 10A and 10B) which may be used in conjunction with spring mechanism 327 or another heart remodeling or surgical procedure such as those known to the art, including U.S. Patent No. 5,702,343 (Acorn), U.S. Patent No. 6,085,754 (Acorn), U.S. Patent No. 5,961,550 (Myocor), U.S. Patent No. 5,800,528 (Abiomed), or those described in McCarthy et al., "Early results with Partial Left Ventriculectomy", from the Departments of Thoracic and Cardiovascular Surgery,  
20 Cardiology and Transplant Center, Cleveland Clinic Foundation, Presented at 77<sup>th</sup> Annual Meeting of the American Association of Thoracic Surgeons, May 1997, 33 pages, all of which are hereby incorporated by reference.

Fig. 36 illustrates an enlarged view of the illustration in Fig. 35. As shown in Fig. 36, spring wires 321 can be covered with a polymer covering 360, such as a polymer such as knitted  
25 polyester, to facilitate tissue ingrowth. Fig. 36 illustrate cross-sections of such covered spring wires 321, respectively, before (left-side) and after (right-side) tissue ingrowth surrounding spring wires 321.

Fig. 37A illustrates an embodiment of an apical stabilization coupling 370, such as an apical cap including a mounting block that rests adjacent the apical portion of the heart and  
30 stabilizes fan-like array 323 adjacent or within an apicandial surface of the heart. In one embodiment, coupling 370 also fixes two or more bundles 320 of spring wires 321 together. Ventricle 331 shown in Fig. 37A has not been subjected to a geometric remodeling device.

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One method of positioning in a heart bundle 320 of wires 321 is shown in Figs. 38-40. As shown in Fig. 38, the bundle 320 of wires 321 can be loaded inside a removable insertion sheath 380. Sheath 380, as shown in Figs. 38 and 39, can then be inserted, for example, through an apical end of the ventricle. After insertion through the apical end of the ventricle, the  
5 removable insertion sheath 380 can be removed, for example, by traction and insertion of a stylus 400, as shown in Fig. 40.

Another embodiment of the present invention is illustrated in Fig. 41. This embodiment includes one or more sections of helical, coiled or corrugated metallic spring wire 410 (referred to as spring mechanism 327) extending from the anterior to the posterior bar or plate 420 (such as  
10 that a min segment 10 described herein) of a bimeridional restraint type of ventricular geometric remodeling device. Spring wire 410 may be of one or more independent wire spring segments without inter-connection or contact, or they may be connected or interwoven during or before placement, or a continual spring segment. In one embodiment, each spring segment is connected at one end to one of the bars or plates 420 on the outside of the anterior wall of a ventricle,  
15 passing through that wall, crossing the inner (endocardial) surface of the interventricular septum and/or of the free ventricular wall, and passing through the posterior ventricular wall on its way to connection with another of these bars or plates 420 on the outer posterior wall. The ends of spring mechanism 327 are anchored to bases or plates 420, which exert force on the assemblies' opposite ends, compressing the ends toward each other, causing the center portion to exert  
20 outward force on the heart wall section that is traversed.

Fig. 42 illustrates another embodiment of the invention. In this embodiment spring mechanism 327 includes a spring assembly 425 anchored to remodeling plates 420 (of a bimeridional restraint type of ventricular geometric remodeling device) on either end and extending across the outer (epicardial) surface of the ventricular free wall from one to the other of  
25 bars or plates 420. At intervals along spring assembly 425, struts 423 (e.g., pins, sutures, cords, cables, etc.) extend through the wall to buttresses 426 on the inner (endocardial) surface, segmentally tethering the spring assembly 425 to the wall so that when the wall moves inward with contraction, spring assembly 425 is also deformed inward.

Another embodiment of the present invention is illustrated in Figs. 43 and 44. In this  
30 embodiment, one or more spring mechanisms 327 including spring assemblies 430 can be introduced into the ventricular cavity by one or more transvascular catheters, and assembled, by manipulation via the placing, for example, of catheters under fluoroscopic and/or echocardiographic visualization and guidance, into an encircling spring assembly 430 on the inner

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surface of the ventricle, lying on the inner surface of the ventricle at or near its largest circumference, between that inner (endocardial) surface and the valve-support apparatus (chordae tendinae 431 and papillary muscle tips 432).

Fig. 45 illustrates a spring mechanism 327 including a U-shaped spring assembly 450 that  
5 can be placed in the ventricle via a transvascular catheter under fluoroscopic and/or echocardiographic control, with attention to orientation and length of the arms of the 'U' so as to avoid deformation and immobilization of the atrioventricular (mitral or tricuspid) valve of the ventricle. The center segment of the 'U' shaped spring assembly 450 can be positioned against the inner surface of the apical portion of the ventricle, while the two arms can be positioned  
10 against the interventricular septum and the free wall.

Spring assemblies 410, 425, 430 or 450 can also include two or more of the assemblies pre-attached to each other at the ventricular end that are separated upon release following trans-apical introduction into the ventricular cavity. Spring assembly 410, 425, 430, or 450 can also allow for adjustment of spring mechanisms after placement to alter the outward force/deformation  
15 relationship. This may be, but is not limited to, local deformation of one or more spring segments by traction or torsion via a transvascular catheter.

#### Method for use

One embodiment of the method of use of devices according to the present invention includes the following steps. First, referring to Fig. 38, each bundle 320 of spring wires 321 is  
20 loaded into a separate removable, generally tubular, polymer sheath. A stab wound is made in the apical end of the ventricle and dilated mechanically, with local pressure to control bleeding. The wire-containing sheath 380 is next introduced, with direction controlled by manual or instrument grasp of the solid post tip 330 of bundle 320. During guiding of the sheathed bundle 420 into the ventricle, position is maintained with the basal end against the inside wall, so as to be  
25 generally between the wall and chordae tendinae and/or valve leaflets. When fully advanced, a stylus is inserted in the outside end of sheath 380 and post tip 330 is maintained stationary while sheath 380 is withdrawn. This releases wires 321 of bundle 320 to 'fan-out' against the inside (endocardial) surface of the ventricular wall. In a preferred embodiment, placement will generally be either against the lateral wall, between the papillary muscles, or against the  
30 interventricular septum.

When the desired number of bundle(s) 320 have been placed, the ventricular apical stab wounds are controlled by purse-string sutures or other mechanical means, with post-tips 330

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protruding. Mounting-block 370 is attached to one or more post-tips 330, so as to control the position of bundles 320 relative to each other (where more than one bundle is used) and to the ventricular wall. In the event of concomitant placement of a ventricular geometric-remodeling device, such as a clasp described herein, post-tips 330 of spring bundles 320 may, or may not, be  
5 fixed to the apical components of the clasp, if any. The mounting block may or may not be adjustable as to separation and relative angulation of post-tips 330.

Fluoroscopy is generally expected to be used during placement, with exposure of the cardiac apex either through a small open incision (intercostal or subcostal) or through a thoracoscope port.

10 Spring mechanisms 327 described above can be made of biocompatible metals such as stainless steel and shape memory metals such as nitinol.

Tethered-Bar (O-Cable Clasp) Device for Bimeridional Cardiac Geometric Remodeling

As discussed above with reference to Fig. 42, for example, the present invention also provides a heart-remodeling device comprised of two rigid main segments 10, designed to be  
15 placed in contact with substantially opposite surfaces of a heart chamber, or of two contiguous heart chambers (such as the left ventricle and left atrium), and held to no more than a desired distance from each other by tethers (such as bands, cords, cables, chains, and the like) joining main segments 10 at their extremities, passing on the outside surface of the cardiac chambers. Such devices are sometimes referred to herein as a clasp or heart remodeling clasp or device.

20 These devices work by pressing inward on the walls of one or more chambers surrounded thereby, altering shape of the chamber or chambers. In doing so, the ratio of wall tensile stress to chamber pressure is reduced.

In common with other variants of bimeridional restraint wall stress reduction devices, and in contrast to other heart-failure treatments, by reducing the ratio of wall stress to chamber  
25 pressure, this device provides the benefit of more effective heart muscle cell contraction that is mediated by cellular afterload reduction, but without the risk of excessive blood pressure lowering.

In contrast with other known variants of bimeridional restraint devices, in most embodiments described herein, spontaneous ventricular torsion is permitted without added  
30 complexity of discrete pivoting joints. In addition, adjustment of bar separation, at either or both ends during or subsequent to placement, is simpler, and more readily adapted to minimally or non-invasive techniques. Furthermore, minimally invasive placement may be facilitated by use of

an initially placed tether or tethers as a guide and traction mechanism for main segment 10 positioning, as shown for example in Figs. 46A, 46B, 47A, 47B, 48A, 48A, 49A, and 49B.

Figs. 46A-53 illustrate several embodiments of devices and components of remodeling devices according to the present invention. Figs. 46A-50B each have a part "A" and a part "B,"  
5 part "A" showing the heart in perspective view through various stages of clasp placement, and part B showing a longitudinal section at the same stage of the placement. This is a non-limiting example in which placement is about the left ventricle 460 and left atrium 461, and positioning of main segment 10 is on the anterolateral and posteromedial aspects of both these chambers. Figs. 46A-49B directly illustrate successive stages in a preferred method of placement, as well as the  
10 structure of the device.

Fig. 46A shows a tether 462, such as a cable, cord, band, chain, guide wire, and the like, that has been passed longitudinally around the heart. Tether 462 can be passed, for example, from the ventricular apex, along the posteromedial surface of the left ventricle, across the posterior atrioventricular junction, through the oblique sinus between the left and the right  
15 pulmonary veins (right side of the left veins, left side of the right veins), through an opening in the pericardial reflection separating the oblique and transverse sinuses, through the left part of the transverse sinus (anterior-superior to the "roof" of the left atrium, on either aspect of the atrial appendage, and posterior-inferior to the left and/or main pulmonary arteries), across the anterior atrioventricular junction, longitudinally across the anterolateral surface of the left ventricle, and  
20 returning to the apex.

Fig. 46A further shows that one end of this tether is attached to what is to become the atrial end of main segment 10. In another embodiment, the main segment 10 may have a channel (open or closed) from one end to the other which allows main segment 10 to be threaded onto a tether 462 after the placement described above.

25 A non-limiting example of a placement method includes placement of an endosurgical access port into the pericardial cavity and introduction of a flexible endoscope through that port as described below (see Fig. 162). The scope could be advanced (with or without supplemental carbon dioxide insufflation and/or positioning the patient with the left posterior chest upward for separation of planes) along the path described above or in the opposite direction, under visual  
30 control. Passage through the pericardial reflection may be achieved by either blunt puncture or nibbling via a flexible endoscopic forceps, such as a grasping or biopsy type as described below (see Figs. 163 and 164). Then, with the port withdrawn, the scope tip may re-exit the pericardial space along side its entry through the port incision. Next, one end of tether 462 (cable or other

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type) could be grasped by a flexible endoscopic grasping forceps and pulled around the heart as the endoscope is withdrawn as described below (see Fig. 165).

Another potential non-limiting example of a placement method includes the use of multiple ports, including one with a video camera and one or more with grasping, pulling, or other manipulating instruments, with or without ancillary CO<sub>2</sub> insufflation.

It is anticipated that imaging techniques, including ultrasonic (transesophageal, surface, or other), magnetic resonance imaging, and x-ray fluoroscopic methods, can also be used to facilitate accuracy and/or ease of placement of tether 462 or subsequently placed components such as main segment 10.

Localized areas or elements of difference radiopacity or ultrasonic response from surrounding areas or elements may be selectively located on the elements to facilitate placement of elements, relative placement of mating members or longitudinal or radial orientation of elements. The latter may be facilitated by configuration of differential localized areas in shapes which vary with rotational orientation.

Fig. 47A illustrates that traction on tether 462 may pull the main segment 10 (e.g., posterior main segment 10) into position below and behind the heart chambers. In one embodiment, a second tether 472 (not shown) can be attached to the opposite end of posterior main segment 10 and that end of second tether 472 can be pulled into the pericardial space along with posterior main segment 10 and an anterior main segment 10 could be slid into position along second tether 472.

In the alternative noted above (of the single tether and non-attached but channel-containing posterior main segment 10), posterior main segment 10 can be threaded onto tether 462 and pushed into position along tether 462 while tether 462 is held stationary.

In either case, an incision whose circumference was, or could be stretched to, the circumference of posterior main segment 10 and any auxiliary parts, would suffice. That incision could be subxiphoid or intercostal near the ventricular apex or basal section of heart, as non-limiting examples.

Figs. 48A-49B show an anterior main segment 10, which has two channels 480 (for example, as shown in Fig. 51A) within main segment 10, one exiting either end, being threaded onto two ends of tether 462, respectively. Each of channels 480 in anterior main segment 10 has an outer end. For a clasp intended to be placed in an open operation, the openings may be in the outer surface of the bar. In a preferred embodiment, a where a heart remodeling clasp is intended

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to be placed in a minimally invasive operation, or a mini-incision operation, the openings of the anterior main segment 10 would continue into a sheath or carrier 481 (not shown) that is quite limp flexurally but stiff compressively. In either case, the separation distance of the anterior main segment 10 from the posterior main segment 10, at either end, may be adjusted at time of or subsequent to clasp placement, by advancing or withdrawing tether 462 into or out of the carrier sheath at its outer end.

Figs. 50A and 50B show an spacer or encasement 500 (e.g., formed of elastomeric material) placed at one or both ends between two main segments 10, surrounding tether 462 between the generally rigid main segments 10. During initial or subsequent tether length adjustment, spacer or encasement 500 can be compressed to varying degrees. The purpose of spacer or encasement 500 is to minimize potential tissue trauma by means of increasing the bearing area contacting the heart and other tissues. In addition, the separation of tether 462 from adjacent cardiac or noncardiac tissue or structures achieves a distribution of force and/or affects tissue response in order to reduce or eliminate risk of trauma to such tissue or structures. Spacer or encasement 500 does not substantially compromise either the freedom of length adjustment of tether 462 or the effect of such adjustment on the net force delivered to the ends of the main segments 10.

Fig. 51A shows a variation in which a tubular enclosing sheath 510, for example of either a solution-cast elastomer or one of the several materials successfully used for vascular grafts (knitted or woven polyester or expanded PTFE, for example) or other materials, is placed over tether 462, either at the time of tether insertion or subsequent to insertion of a heart remodeling clasp placement. Main segment 10, with or without spacer or encasement 500, are then inserted over tether 462 and within sheath 510. Sheath 510 may be of uniform diameter, but is preferentially of varied caliber to fit the varied component circumferences. In the case of caliber variation, it may be necessary for sheath 510 to be sufficiently elastic to allow passage of larger members.

Figs. 51B-51E illustrate additional embodiments of spacer or encasement 500. Fig. 51b illustrates a tube 520 which is made from a porous material that is of stable circumferential dimension but freely compliant in length (within a desired predetermined operating range) to applied compressive or tensile force. An example criterion for free length compliance is, for example, that tube 520 alone will require less than 0.1N of either tensile or compressive force to either lengthen or shorten, respectively, the entire range of its operation.



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Examples of spacer or encasement 500 include tubes shown in Figs. 51B-51E. Fig. 51B shows, as noted above, a tube 520 made of porous, surface crimped corrugated fabric such as commercially knitted, woven, or braided vascular prostheses or custom-fabricated approximations of such tubes. A typical material of construction is polyester. Expanded polytetrafluoroethylene (PTFE) tubes without outer membrane jackets or other reinforcement means are also useable (as shown in Fig. 51c), as are woven or loosely (e.g. <20 yarn-count/inch) diagonal-braided yarn tubes (as shown in Fig. 51d). Fig. 51e illustrates a tube 520 as shown in Fig. 51c and having holes or perforations (such as round, rectangular, diamond shaped, etc.) along its wall to allow for tissue ingrowth after placement. Fig. 52 shows the addition of an adjustable control mechanism 26 including adjustability canister 530 (for example, for adjusting a distance between main segments 10 and/or the size and shape of stabilizer/reconfiguration segment 12), which may be placed at some distance from the heart such as, for example, the subcutaneous tissue of the abdomen or prepectoral region. Fig. 53 shows another perspective of such a clasp with adjustability canister 530.

Adjustability canister 530 can be used to adjust by non-invasive, minimally invasive, and/or invasive procedures, a distance between main segments 10 and/or the size and shape of stabilizer/reconfiguration segment 12. Canister 530 can be accessed, for example, under local anesthesia by an open incision that allows tightening or loosening of a screw mechanism by an instrument (e.g., allen wrench or screwdriver) to advance or retract the length of tether 462. Canister 530 can also be accessed under local anesthesia and a skin/tissue-penetrating instrument such as a flat or triangular tipped (Keith) surgical needle used to engage a screw mechanism through a self-sealing elastomeric plug. Canister 530 could also contain a ratchet mechanism with a permanent magnet affixed, so that a varying magnetic field at skin surface, generated either by a moving a permanent magnet or a solenoid, may advance or retract the length of tether 462. In addition, canister 530 can have a compressible diaphragm on the surface nearest the skin, which may be cyclically compressed, engaging a ratchet mechanism to advance or retract the length of tether 462. Furthermore, canister 530 can have an electrochemical cell (batteries), geared electric motor, and appropriate assembly, that when actuated may advance or retract length of tether 462. In one embodiment, adjustable control mechanism 26 is programmable from outside by radio or magnetic signals such as used in programmable pacemakers or radio-controlled toys in ways familiar to those experienced in these fields of technology. Adjustable control mechanism 26 such as canister 530 may include position sensors and electronics for telemetric detection of position by the programming device. In that event, it may or may not have a feed-back servo mechanism

whereby the external programmer may have the desired position or desired movement or desired force entered as a digital or analog signal.

#### Alternate Heart Remodeling Clasp

Fig. 54A shows one embodiment of an improved type of main segment 10 of a heart-remodeling clasp according to the present invention. It is similar to other main segments 10 in that it employs bimeridional restraining segments 540 to reduce the wall-tension/chamber-pressure ratio. Bimeridional restraining segments 540 include middle segment 541, and one or more shoulder sections 542 connected together and to middle segment 541 by hinges 543. In one embodiment, a traction cable 544 is anchored to one of end segments 542 at point 545 and passes through shoulder segments 542 and segment 540 via openings 546. In one embodiment, openings 546 are located opposite hinges 543 as shown in Fig. 54B.

As traction cable 544 is tensioned and pulled through openings 546 in the direction of arrow 547, shoulder segments 542 and bimeridional restraining segments 540 are configured into the position shown in Fig. 54B where hinges 543 are closed. As the tension on traction cable 544 is released, the bimeridional restraining segments 540 can return to the position shown in Fig. 54A. By tensioning or releasing the tension on traction cable 544, bimeridional restraining segments 540 on the natural heart surface can be tensioned or released to the desired position to accommodate and/or assist systolic and diastolic function of the heart.

Figs. 54E and 54F show an embodiment of main segment 10 such as that shown in Figs. 54A and 54B except the relative width of each segment is larger.

#### Adjustable Stabilizing and/or Reconfiguration Segments

In one embodiment, as shown in Fig. 55, a heart remodeling clasp according to the present invention includes main segment 10 having compression segment 550, shoulder segment 551, and adjustable closure 552. Compression segment 550, for example, includes in one embodiment the features of segment plates 170 shown in the Figs. 17-31. Adjustable closure 552 can be any adjustable closure that will join main segments 10 and compression segments 550 at the top and bottom of the clasp. In one embodiment, adjustable closure 552 includes adjustable cable or strap 553, and releasable lock 554, as shown more specifically in Figs. 61 and 62.

The heart remodeling clasp according to the present invention can also be used with adjustable stabilizer/reconfiguration segments 12 as shown in Figs. 56 and 58. Adjustable stabilizer/reconfiguration segment 12 are used to (a) stabilize the main segment 10 in position on the natural heart as shown, for example, in Figs. 63a and 63b and/or (b) to reconfigure one or

more portions of the natural heart as shown in, for example, Figs. 5, 7, 8, 10A, 20B, 11A, 11B, 12A, 12B, 13A, 13B, 14A, and 14B.

Adjustable stabilizer/reconfiguration segments 12 are configured to fit the particular shape of the portion of the natural heart on which they are to be located. For example, adjustable  
5 stabilizer/reconfiguration segments 12 can be configured as shown in Figs. 56, 58, 63A, 63B, or as shown, for example, in Figs. 5, 7, 8, 10A, 10B, 11A, 11B, 12A, 12B, 13A, 13B, 14A and 14B. Adjustable stabilizer/reconfiguration segment 12 is flexible, semi-rigid or rigid depending on intended placement and use thereof. In one embodiment, adjustable stabilizer/reconfiguration segment 12 is attached to the clasp by slipping ends 560 (as shown in Figs. 56 or 58) thereof  
10 through attachment clips 556 or any other means for adjustably attaching stabilizer/reconfiguring segment(s) 12 to the clasp. Attachment clips 556 are configured as shown in Figs. 55, 57a, 57b, 59a, 59b, and 59c and are attached to the clasp via attachment pins 601 (shown in Fig. 60) at a location on the clasp to achieve the desired stabilization and/or reconfiguration. For example, attachment clips 556 can be attached adjacent the shoulder segment 557 or at any point along the  
15 compression segment 550, as shown in Fig. 55.

It should also be noted that the spacers or encasements 520 discussed above with respect to Figs. 50A and 51A-51E, could also be used to cover adjustable cable or strap 553, or any other part of the main segment 10 or adjustable stabilizer/reconfiguration segment 12 where the direct contact of the heart is undesirable.

In one embodiment shown in Fig. 55, shoulder 557 is configured to fit adjacent the  
20 atrioventricular groove and compression segment 550 is configured to fit adjacent (e.g., on) the left ventricle. If main segment 10 starts to slip off the natural heart 1, tension in adjustable stabilizer/reconfiguration segment 12 created by such slippage increases to prevent main segment 10 from slipping off the natural heart or a portion thereof, as shown diagrammatically in Figs. 65-  
25 67.

Fig. 65 shows two lines of orientation, line 650 which illustrates the situation where main segments 10 are positioned 180° from each other, and line 651 which illustrates an off-center positioning between main segments 10. The degree of offset can vary, but is preferably is in the range of between 145° and 180°. In Fig. 66, main segments 10 are held in place by one or more  
30 pieces of material making up stabilizer/reconfiguration segment 12 on the lateral side of the heart and one or more additional pieces of material making up stabilizer/reconfiguration segment 12 on the right ventricular side of the heart.

Fig. 67 shows the same embodiment as illustrated in Fig. 66, but from a side perspective using a stabilizer/reconfiguration segment 12 that is relatively wide compared to the size of the heart being treated. The orientation of main segments 10 can be placed on a heart without regard to the internal structure of the heart as required for devices internal to the heart. Accordingly, main segments 10 can be placed on the heart and achieve increased heart function (e.g., increased ejection fraction and decreased valvular regurgitation), as are not experienced with many internal devices.

All elements are configured to fit the particular portion of the heart on which they are to be placed. For example, as shown in Figs. 63a, 63b, 64a, and 64b, closure segments 552 can be configured to bridge the basal portions and apical portions of the natural heart.

#### Alternative Adjustable Stabilizing/Reconfiguration Segments Clasp with Pacing Leads

The present invention is also directed to an adjustable stabilizing/reconfiguration segment 12 for use with transceivers or pacing leads 694 capable of receiving and transmitting electrical signals, for example from a pacemaker. Referring to the figures, an exemplary natural heart 1 is shown in Figs. 68, 70 and 71.

A natural heart 1 has a lower portion comprising two chambers, namely a left ventricle 2 and a right ventricle 3, which function primarily to supply the main force that propels blood to and from the lungs, and the peripheral circulatory system, which propels blood through the remainder of the body. Natural heart 1 also includes an upper portion having two chambers, a left atrium 3 and a right atrium 4, which serve as an entryway to the left and right ventricles 2 and 3, respectively. As shown in Fig. 68, adjustable stabilizing/reconfiguring segment 12 includes one or more straps 680 (e.g., which may be suturable) which encircle the heart and are secured to any one or more of the main segments 10 described in this application, including a U shaped member segment as more fully described in U.S. Patent Application No. 08/035,710, incorporated herein by reference, with sutures.

Figs. 69A and 69B show alternate constructions of the main segment 10 and straps 680. In Fig. 69A, a cross-section is shown in which main segment 10 is encased in a suturable material encasement 690 such as a porous or non-porous material such as polyester mesh, woven polyester, silicone rubber, polyester fabric or reinforced silicone. Encasement 690 about main segment 10 provides a means for attaching straps 680 to main segment 10, which itself may be formed of material that would accept a suture. In Fig. 69B, main segment 10 is formed such that its exterior surface includes encasement 690, shown held in between two projections 691 in main

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segment 10. In this embodiment of the present invention, sutures 693 may be passed through straps 680 into encasement 690 held to main segment 10. Sutures 693 (not shown) in both Figs. 69a and 69b.

5 As shown in Fig. 68, several adjustable stabilizing/reconfiguration segments 12 may be used to help maintain main segments 10 in position on the natural heart. Fig. 68 shows three adjustable stabilizing/reconfiguration segments 12 in position with two additional adjustable stabilizing/reconfiguration segment 12 crossing over the top of the natural heart. Thus, in this embodiment, five (5) stabilizing/reconfiguration segments 12 are used.

10 As shown in Fig. 70, the anchoring of adjustable stabilizing/reconfiguration segments 12 may take the form of a soft harness such as porous (e.g., a suturable mesh) or non-porous material. In this embodiment, adjustable stabilizing/reconfiguration segments 12 are wrapped about the natural heart and sutured to a suturable material encasement 690 of the main segment 10 as shown in Figs. 69A and 69B. Adjustable stabilizing/reconfiguration segment 12, for example, may be formed of any biocompatible material and may be relatively narrow or may cover a  
15 relatively wide swath across the natural heart as desired by the surgeon.

As shown in Figs. 71 and 72, adjustable stabilizing/reconfiguration segments 12 alternatively include one or more rigid, semi-rigid or flexible bands 710 that are designed to encircle the heart and include clamping mechanism 720, or the like, at each end of adjustable stabilizing/reconfiguration segments 12 which cooperate with an engagement mechanism 721  
20 attached to or integral with main segment 10. As shown in this embodiment, clamping mechanisms 720 are ball snaps 722 which engage receptacles 723 in the engagement mechanism 721. In this form of the present invention, entire band 710 may be formed of a rigid, semi-rigid or flexible material. Alternatively, the ends thereof might be formed of such a material and the remainder of the band 710 may be configured like straps 680 as shown in Figs. 68 and 69a, with  
25 the clamping mechanisms 720 being as shown in Fig. 72. In addition, any other type of adjustable attachment mechanism or non-adjustable mechanism, such as clamps, may be used to secure adjustable stabilizing/reconfiguration segments 12 to main segment 10.

In certain embodiments of adjustable stabilizing/reconfiguration segment 12 according to the present invention, several distinct regions are formed which may be utilized to hold and carry  
30 transceivers or pacing leads 694 which extend from or through the adjustable stabilizing/reconfiguration segments 12. Transceivers or pacing leads 694 also can be placed on the main segment 10 as shown in Fig. 68 in phantom. There may be one or more pacing leads and/or transceiver elements (e.g., elements capable of sending and receiving, both from the heart

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and electrical devices, electrical signals) as desired such that pacing or other manipulation or diagnosis of the heart may be readily accomplished.

In some cases, the stabilizer/reconfiguration segment may be sized to be slightly shorter than the exterior heart wall which it traverses so that it exerts a continual inward pressure on the wall and thus serves to reconfigure the heart in that location. In other embodiments, the  
5 stabilizer/reconfiguration segment is sized to exert little or no inward force on the heart wall and thus serves only as a stabilizer element.

#### Catheter Based System to Reduce Myocardial Wall Tension

The present invention is also directed to a method for placing restructuring or other  
10 devices into one or more chambers of the heart. In one embodiment, the method according to the present invention includes a catheter based system that may be used to place a system such as that shown in U.S. Patent Application No. 08/035,710 or U.S. Patent No. 5,961,440, both of which are hereby incorporated by reference.

In the present method, as shown in Figs. 73A-75B, via an artery leading to the ventricle,  
15 a catheter 730 is positioned within the left ventricle 2 in a non-invasive or minimally invasive procedure. A reversibly collapsible anchor 731 in the form of a clamshell or umbrella in its collapsed form is pushed outwardly through the left wall of left ventricular 2. This insertion of a reversibly collapsible anchor 731 through the wall may be aided with intravascular ultrasound. Once through the wall, anchor 731 opens to provide a nail or rivet-like planar surface that is then  
20 pulled back against the external surface of the wall. The same deployment of a second anchor 731 occurs on another portion of the wall of the left ventricle 2, for example on the wall of left ventricle 2 opposing the location of first anchor 731. Wires, cables or cords 732 attached to the anchors 731 are then connected and tightened, thereby decreasing this left ventricular dimension, and exerting a continual inward pull on the chamber walls, indenting the walls and reconfiguring  
25 the chamber. In one embodiment, a single wire, cable or cord 732 is used.

Fig. 74A shows anchor 731 open against the exterior wall of the left ventricle 2 after the two cords 732 have been placed. Fig. 74B shows the final cord 732 after joining and tightening of the two cords 732 originally placed. Figs. 75A and 75B show clamshell anchoring mechanisms which work in the same manner as the umbrella embodiment described above. The  
30 umbrella-like anchor may also include a head which when elongated is an elongated planar configuration rather than round so that pressure applied against the exterior surface of the heart creates an elongated indentation in the chamber.

By using the method of inserting transventricular reconfiguration members described above according to the present invention, the surgeon can avoid opening the patient's chest wall.

#### Delayed-Penetration Pegs for Epicardial Fixation

5 In certain embodiments, the invention also provides local stabilization and/or fixation of elements of heart remodeling clasp-type reconfiguration devices according to the present invention. Such elements may include elements that assist in stabilizing a surface of a natural heart. As shown in Figs. 76a, 76b and 76c, cross-sections of clasps according to the present invention (for example those shown in Figs. 1a, 3, 7, 10A, 10B, 53, 55, ) can be stabilized and/or fixed to the surface of the natural heart by one or more stabilization protrusions 174 in the  
10 form of pegs or studs designed for delayed penetration into the natural heart surface 1. Stabilization protrusions 174 may be attached to or integral with main segment 10 and/or adjustable stabilization/reconfiguration segment 12.

Stabilization protrusion 174 is particularly adapted to devices which, by their nature, are kept pressed against the natural heart surface 1 and for which the major risk is tangential  
15 displacement.

Stabilization protrusions 174, for example, have three main embodiments: (1) permanent protrusions or pegs; (2) fully or partially absorbable protrusions or pegs; and (3) extendable protrusions or pegs; and combination of the same. Extendable protrusions or pegs 174 can be either permanent or partially absorbable.

20 The principle of the stabilization protrusion 174 according to the present invention is as follows. The length of stabilization protrusion 174 is somewhat longer than the diameter of stabilization protrusion 174. Stabilization protrusion 174 can be of any cross sectional profile. A preferred profile is generally circular, with a relatively blunt hemispheric tip.

In one embodiment, more than one stabilization protrusion 174 is formed integral with  
25 main segment 10 in a single line along the length of stabilization protrusion 174. Each stabilization protrusions 174 are separated from one another by a space, for example, at least twice the length of an individual stabilization protrusion 174. Due to differing heart wall thicknesses of an individual, optimal penetration of stabilization protrusion 174 into natural heart surface 1 is determined experimentally. The maximum stabilization effect is thought to occur at  
30 the maximum penetration of stabilization protrusion 174 that will not damage the epicardium during brief (e.g., approximately < 15 minutes) trial placements. This strategy is intended to allow movement one or more times during the placement operation, based on gross,

echocardiographic, or other assessment.

Stabilization protrusions 174 are thought to work because initially the relatively tough epicardial layer of natural heart surface 1 is deformed at the site of pressure by stabilization protrusions 174 in a tent-like fashion downward into the natural heart surface, as shown in Fig. 76B. The muscle fibers and blood vessels 761 are free to move for short distances and will be displaced to one or the other side without damage. The 'tented' epicardium, so viscoelastically deformed, acts to counter potentially displacing tangential forces and thus to stabilize in position. Referring to stabilization protrusion 174, pressure on the very small surface area at the tip of stabilization protrusion 174 is quite high, approximately 1 to 5 megaPascals (7,500 to 37,500 mmHg). This pressure causes very localized tissue death or necrosis followed by loss of mechanical integrity. The epicardium will then separate, and the margins of the hole created in the epicardium surround the sides of the stabilization protrusion 174 toward the bar as shown in Fig. 76c. At this time, the muscle fibers and blood vessels 761 continue to be displaced to the sides of stabilization protrusion 174. Position stabilization for stabilization protrusion 174, and thus of the main segment 10 or stabilization/reconfiguration segment 12, is maintained.

There is a tendency for devices such as heart remodeling clasps including main segments 10 and/or stabilizer/reconfiguration segment 12, according to the present invention which are applied to the surface of the heart to become displaced tangentially due to the motion of the heart. This has particularly been observed, for example, in the acute experimental trials of clasps according to the present invention, in the absence of such local stabilization means.

The likelihood is that a broad-based area of fixation of an epicardial-contacting device would 'splint' or immobilize the layers of myocardium immediately subjacent to the device, such that part of the muscle mass could not effectively contribute to heart function. This could occur with stabilization protrusion 174 if placed along the width of main segment 10 as shown in Figs. 79C and 79D. Accordingly, in one embodiment stabilization protrusions 174 are confined to a narrow longitudinal centerline of a device such as main segment 10 of a heart remodeling clasp according the present invention, as shown in Fig. 79a. In Fig. 79a, only the first of multiple stabilization protrusions 174 are shown on main segment 10 in a top view in cross-section of main segment 10. In such devices, stabilization protrusions 174 may be an improvement over or used in addition to local fixation means such as adhesives and those methods and devices that promote scar tissue.

Stabilization protrusions 174 are different from sutures in that the protrusions do not require complex manual or instrumental manipulation to place. It is different from tacks or spikes



in that blunt configuration of stabilization protrusions 174 delays penetration. It is different from adhesives in that effective fixation is only in the tangential direction and in that local transverse shortening of the heart is not restrained. It is different from methods that promote scar tissue fixation in that stability is immediate.

5           Relative to sutures, the devices with stabilization segments offers fixation with no complex manual or instrumental manipulation at the site of fixation, which is of great potential value in minimally invasive placement of the devices to be stabilized. Relative to sharp spikes or tacks, risk of coronary damage is expected to be greatly diminished. Relative to adhesives, the tangential-only fixation allows removal and repositioning any number of times without harm  
10           during placement, until position is acceptable. Relative to reliance on scar tissue formation, fixation is immediate.

            Stabilization protrusions 174 according to the present have several embodiments, including permanent pegs, fully or partially absorbable pegs, and extendable pegs or combinations of the same. The permanent relatively blunt stabilization protrusions 174 (such as pegs) are  
15           rigid, nonabsorbable posts of the type shown in Figs. 76A-76C, which extend, generally perpendicularly, toward the natural heart surface 1 from main segment 10.

            In another embodiment, as shown in Figs. 77A, 77B and 77C, stabilization protrusions 174 are fully or partially absorbable pegs having a rigid component made of a fully or partially absorbable biomaterial. In this embodiment, stabilization protrusions 174 may also include a  
20           porous (for example a flexible or rigid) component 770 (shown in cross-section in Figs. 77A, 77B and 77C) such as a flat or tube-like mesh, wire or net that is not absorbable and which extends into or is attached to main segment 10. The Porous component 770 is embedded in or may surround the rigid or semi-rigid component of stabilization protrusions 174. In this embodiment, the penetration mechanism is as for the stabilization protrusions 174 described above.  
25           Stabilization protrusions 174, exposed over time to tissue fluid and the agitation of cardiac motion at all surfaces, begin to dissolve and/or is partially absorbed (Fig. 77B) or fully absorbed (Fig. 77C) by the heart tissue, depending on the material of which stabilization protrusions 174 are composed. If stabilization protrusion 174 includes a flexible porous component exposed before, simultaneous with, and after full or partial absorption of the rigid component, the healing process  
30           of the myocardium which has been damaged by fiber separation, may cause collagen fibers to penetrate interstices in the porous component 770.

            In another version of this embodiment, as shown in Figs. 80a and 80b, stabilization protrusion 174 includes a rigid or semi-rigid non-absorbable head 800 (e.g., formed of a

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biocompatible polymer), a rigid or semi-rigid partially or fully absorbable tip 801, and a non-absorbable porous component 770 (e.g., a flexible or rigid mesh, wire or net). As shown in Figs. 81A and 81B, head 800 is attached to main segment 10 by any mechanical or chemical means. Then, stabilization protrusion 174, by delayed penetration as discussed above with respect to  
5 Figs. 76A-76C, penetrates natural heart surface 1 by delayed penetration (the end result of which is shown in Fig. 81B), after which partially or fully absorbable tip 801 is absorbed as shown in Fig. 82A. The healing process of the myocardium which has been damaged by fiber separation causes collagen fibers to penetrate interstices in the porous component 770 as shown in Fig. 82B.

The composition of the stabilization protrusion 174 is selected and/or treated such that it  
10 will provide tangential stability of stabilization protrusion 174, and thus of main segment 10, on natural heart 1 until it is fully absorbed i.e., the stabilizing effectiveness of the rigid component continues until it is fully absorbed. The materials for fully or partially absorbable protrusion 174, or portions thereof, will ordinarily be selected to be partially or fully absorbable over a predetermined period of time.

15 Another embodiment of stabilization protrusion 174, as shown in Figs. 78a and 78b, according to the present invention is a spring-loaded, length-extending protrusion or peg. According to this embodiment, stabilization protrusions 174 have first and second sections 781 and 782, separated by a releasable holding mechanism 783 such as a wire or similar element, and a spring, elastic or tensioned band or wire 784, or similar element.

20 Stabilization protrusions 174 are initially engaged with natural heart surface 1 as discussed above up to the length of second section 782. After this initial penetration depth has been achieved, the penetration depth may be increased immediately or after a period of time by removing releasable holding mechanism 783 and allowing band or wire 784 to push stabilization protrusions 174 into natural heart surface 1 to an optimal depth.

25 This embodiment provides an initial limited penetration in the natural heart surface by stabilization protrusions 174 controlled by releasable holding mechanism 783, which opposes the extending force of band or wire 784. In one embodiment, band or wire 784 is formed of a silicone rubber strip. After main segment 10 is positioned on natural heart surface 1, releasable holding mechanism 783 is released, and the elastic or tension force of band or wire 784 causes  
30 stabilization means to penetrate natural heart surface to an optimal predetermined depth. Resistance of muscle fibers to displacement may or may not cause a detectable delay in full penetration.

The material of the spring-loaded or tensioned, length-extending stabilization protrusions 174 may be totally non-absorbable as in the permanent stabilization protrusions 174, and may be porous or non-porous.

5 The materials forming the stabilization protrusions 174 may be porous or non-porous. A porous material may be used to promote tissue in-growth into stabilization protrusions 174. As discussed above, the materials may also be non-absorbable, or partially or fully absorbable.

Flexible Sheath Containing Rigid Segments and/or Rigid Adjustable Segments

As shown, for example, in Fig. 83, the present invention is also directed to a flexible sheath 830 containing rigid adjustable or non-adjustable mating segments configured to be linked  
10 together to form main segment 10. Figs. 83, 84A, 84B, 85A, 88B, 88C and 85D illustrate an embodiment of flexible sheath 830 which is placed around natural heart 1 or a portion thereof. Individual segments, for example first, second and third segments 850, 851, and 852, respectively, are then slipped into sheath 830 as shown in Fig. 86A, 86B, and 86C. As discussed more fully below, individual segments 850, 851, and 852 may be flexible, rigid, or semi-rigid  
15 and may be interlocking or non-interlocking, depending on the particular remodeling effect desired on natural heart 1 or a portion thereof. Segments 850, 851, and 852 may also be contoured as shown in Figs. 86A-86C to effect a desired shape change. A fourth segment 854 (as shown in Fig. 85D) (which may also be contoured) has its own flexible sheath 854. Main segment 10 may be formed from any number of these individual segments.

20 Fig. 83 shows a flexible sheath 830 in accordance with the present invention. Figs. 84A and 84B illustrate two views (84A a perspective view, and 84B a sectional view) of natural heart 1 with a flexible sheath 830 adjacent heart 1. Fig. 85A, 85B, 85C and 85D show a set of rigid segments 850, 851, 852, and 853. These segments are configured to hinge or pivot against each other at ends with lateral stability provided by flexible sheath 830. First, second, third, and  
25 fourth segments 850, 851, 852, and 853, respectively, shown in Figs. 85A, 85B, 85C and 85D may or may not be interlocking. Figs. 86A, 86B and 86C, however, show a preferred embodiment of first and second segments 850 and 851 in which the segments are interlocking in this example by use of a ball and socket joint. Flexible push rod 865 is used to position the segments within sheath 830. Fig. 86F shows an enlarged cross-sectional view of the final end  
30 joining shown in Fig. 86E.

In accordance with principles of the present invention, flexible sheath 830 containing first, second and third segments 850, 851, and 852, respectively, can be assembled as follows.

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Referring to Figs. 86A, 86B, 86C, 86D, 86E and 86Ff, first segment 850 (for example, basal segment for placement near basal portion of heart) is inserted into the tube using flexible push rod 865. Next, second segment 851 (for example, an anterior segment) is inserted into flexible sheath 830. Second segment 851 is then click-locked onto first segment 850. Next, third segment 852 (for example, a posterior segment) is inserted into flexible sheath 830 and is then click-locked onto the first segment 850. Fourth segment 853 (for example, for placement near apical portion of the heart) is then inserted into its own flexible sheath 864 and is snapped into place with second and third segments 851 and 852 as shown in Figs. 86E, 86G, and 86H such that flexible sheath 864 on fourth segment 853 meets and seals with the flexible sheath 830 on second and third segments 851 and 852.

Another aspect of the present invention relates to apparatus and methods for altering the length or curvature of main segment 10. Fig. 87 shows a portion of a segment including a pull-cord version of a chain of hinged block forming, for example, a main segment 10 according to the present invention. As shown in Fig. 87, a series of blocks 870 having pivot pins 871 on one side, tapered edges 878 forming gaps 872 (see Fig. 89) on the opposite side, and a cable, cord or wire 873 attached to one of blocks 874 at one end of main segment 10. When the cable, cord or wire 873 is pulled, the side of the assembly on which blocks 870 have gaps is tightened and individual blocks 870 pivot around pins 871, with gaps 872 closing and blocks 870 coming into contact, thereby shortening that margin and bending the whole segment. Although only four blocks are shown in figure 87, any number of many more or less blocks can be used to form the desired length as shown in Fig. 89. As shown in Fig. 87, one of end blocks 874 is a cable-entry block, which is fixed to cable or cord or wire 873. When cable, cord or wire 873 is moved relative to the blocks 870, the other of end blocks 874 containing an end of cable, cord or wire 873 moves relative to the first end block 874 and main segment 10 bends. In one embodiment, one end of cable, cord or wire 873 is threaded into one of end blocks 874, and as a user winds or unwinds cable, cord or wire 873 into one of end blocks 874, one end of main segment 10 moves relative to the other end of main segment 10 and the segment bends. Although described with respect to main segment 10, the structure shown in Fig. 97 can be used for any of segments 850, 851, 852, or 853. Fig. 88 shows one example of two blocks 870 and one pin 871. Holes 877 receive cable, cord or wire 873.

In one embodiment, shown in Fig. 89, main segment 10 has a flexible outer sheath 890 which, for example is corrugated or smooth mesh, as in Figs. 51B, 51C, 51D, 51E, 69A, 69B, and 83.

Additional mechanisms according to the present invention for adjusting curvature are described below. For example, Fig. 90 shows an embodiment where an end of cable, cord or wire 873 is threaded and is designed to rotate at its end when twisted remotely so as to bring portions of blocks 870 together and close gaps 872. In the embodiment illustrated in Fig. 90, as cable 873 is turned, block 874 is pulled closer to its adjacent block 870, closing gap 872. In turn, all blocks 870 comprising main segment 10 are pulled around their respective pins 871 so as to increase the curvature of the overall segment. In an alternative embodiment, the cable, cord or wire 873 is be pulled axially to shorten it and tighten the blocks 870 around their respective pins 871. Alternative embodiments can also achieve the objective of changing the bending moment, or curvature, of a segment according to the present invention, thereby effecting the radius reduction of a chamber of the natural heart.

Another such example is illustrated in Figs. 91A, 91B, 91C and 91D, wherein a remodeling member in the form of flexible strip 910 has a cable, wire, or cord 911 disposed through one side of it. When the cable, cord, or wire 911 is shortened, for example by pulling, strip 910 tightens and curves to the side of the cable, wire, or cord 911, as shown in Figs. 91A and 91B. Figs. 91C and 91D illustrate a slightly different embodiment where two cables, cords, or wires 912 are both disposed within strip 910 for adjusting curvature of strip 910. This allows a balancing of forces and easy reopening of strip 910 by pulling on cable, cord, or wire 911 on the side opposite the curvature.

Another embodiment could be used to provide the bending moment discussed above. Figs. 92A and 92B illustrate the use of hydraulics to achieve the change in bending moment. Flexible segment 920, which is not stretchable in a longitudinal direction, but which is bendable, is connected on its ends to a flexible, corrugated sheath 921 having a cavity 922. The sheath is inflated with a fluid as shown by the arrow in Fig. 92b, and pressure within sheath 921 causes the segment to bend in the direction dictated by flexible segment 920 using upper teeth 925 to expand and lower teeth 921 adjacent flexible segment 920 to compress. As the fluid is allowed to evacuate cavity 922, the teeth return to their released state and main segment 10 straightens, as shown in Fig. 92A.

The present invention also provides additional mechanisms and embodiments for modifying the length and/or curvature of main segment 10, thereby effecting the radius reduction of a chamber of the natural heart. For example, Figs. 93a and 93b illustrate a series of telescoping segments 930 which are narrow at one end and wider at the other, each narrow end being a male end and each wider end being a female end to allow variance in the length of the

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overall segment. In this embodiment, a cable, cord or wire 931 is run throughout telescoping segments 930. At each end of main segment 10 are ends 932 which for example in this embodiment, have the male and female ball and socket joints as described above for adjoining several segments to each other. Optionally, a sheath 933 also surrounds the telescoping segments 930. Fig. 93B shows the effect of shortening main segment 10, for example by pulling the cable or wire or cord 931.

As described above, various mechanical means may be utilized to shorten cable, cord, or wire 931, such as simply pulling it, or using a threaded torsion end which moves in and out of end 932 as the cable, cord, or wire 931 is rotated. Moreover, any appropriate hydraulic or mechanical means may be used to shorten the overall length of the main segment by taking advantage of the series of telescoping segments 930.

Figs. 94 and 95 also show the use of a hydraulic system to change the length of a segment according to the present invention comprised of a series of telescoping segments 930. As shown in Fig. 94, as a fluid is pumped into the hollow segments 930, the pressure increases and segments 930 separate, increasing the overall length of main segment 10. Fig. 95 shows a similar embodiment but where the telescoping segments are of a slightly smaller width relative to their length.

Fig. 96 shows another embodiment useful for adjusting the length a segment according to the present invention. In this case, telescoping tubular segments 960 are placed over a cable 961. Cable 961 is also fixedly attached to a threaded segments 962 and 963 on each end of main segment 10. Each threaded segment 962 and 963 is disposed within an appropriate thread accepting housing 964 and 965 at each end of main segment 10. Threaded segments 962 and 963 are disposed opposite each other so that rotation of the cable 961 in one direction causes compression between the two threaded ends. In this embodiment, optionally a sheath 966 surrounds telescoping segments 960.

Cable 961 can be rotated mechanically or electromechanically from a local or remote source. In the case of electromechanical rotation of cable 961, an appropriately geared motor may be used to rotate or torque cable 961 or it can be interposed along the cable itself. In the embodiment is shown in Fig. 97, cable 972 is rotated via motor 970 which is powered and controlled by wires 971. Motor 970 may be within or outside the patient.

In another embodiment, hydraulics similar to those was discussed above, may be used to supply fluid pressure to telescope main segment 10. Fig. 98 shows an embodiment where a

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hydraulic fluid is used to bias a piston rod rather than filling a telescoping segment as discussed above. In this embodiment, a piston 980 is filled or evacuated which results in the movement of a piston rod 981 outward or inward, respectively, thereby moving telescoping segments 982. Because piston rod 981 is attached to the adjacent telescoping segments, desired movement of the segments is thereby achieved.

A combined length adjustment and curvature adjustment of one or more of any of the segments according to the present invention can be accomplished by combining the elements as discussed above. This is especially beneficial when trying to adjust both the length and curvature of main segment 10 so that it properly and completely contacts the individual patient's heart surface, thereby effecting the radius reduction of a chamber of the natural heart. Figs. 99A, 99B, and 99C show that the elements discussed above can be combined to create, for example, a main segment 10 configured for use adjacent a basal or apical portion of the natural heart. Fig. 99A shows an embodiment where the segment can be adjusted from arc (1) to arc (2) where arc (2) has a lesser length than, lesser angle of curvature than, and the same radius of curvature, as arc (1). Fig. 99B shows that the segment can be adjusted from arc (1) to arc (2) where arc (2) has the same length as, a greater angle of curvature than, and a lesser radius of curvature than arc (1). Fig. 99C shows that main segment 10 can, with proper balance of the elements discussed above, be adjusted from arc (1) to arc (2) where arc (2) has a lesser length than, a lesser radius of curvature than, and the same angle of curvature as arc (1).

#### Assembly for Minimally Invasive Adjustment

The present invention also provides an assembly for minimally invasive position adjustment of the devices of the present invention, including main segment 10 and/or adjustable stabilizer/reconfiguration segment 12 as described herein, or other devices. The adjustment assembly of the invention can be positioned near the skin surface to which adjustments may be made, for example, by one or more skin-penetrating needles or open exposure through one or more small incisions, and non-invasive or minimally invasive procedures.

The adjustment assembly can include, for example, a control means, such as control means 1000 (such as canister 520 in Figs. 52-53) illustrated in Fig. 100, that is positioned similar to the position of cardiac pacemakers, percutaneous intravenous infusion ports, or percutaneous dialysis access sites.

The adjustment assemblies of the present invention can include a coupling and a mechanism internal to the clasp itself to adjust the spacing between two main segments 10, such

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as those shown in Figs. 101A, 101B, 101C, 101D, 101E, 102, 103, 104, and 105A-114B. The coupling is positioned between the superficial mechanism and the mechanism internal to the clasp. The clasp internal mechanism is located within or upon one or more components of main segment 10 which responds to superficial mechanism adjustment by effecting a change in the relative position of the heart-contacting surfaces of two or more main segments 10 related to one another, of some portion or portions of main segment 10, and/or of the adjustable stabilizer/reconfiguration segments 12.

An embodiment of an adjustment assembly of the invention is illustrated in Figs. 101A, 101B, 101C, 101D and 101E. In this embodiment, rotation of a cable 1010 effects a change in the position of main segment 10 and/or adjustable stabilizer/reconfiguration segment 12. As shown in Fig. 101A, cable 1010, such as a cable, cord, wire, is located within a casing 1012 and is attached to main segment 10 and/or adjustable stabilizer/reconfiguration segment 12 (not illustrated). A tip 1013 (shown in Fig. 101B) of cable 1010 is covered by cap 1012 that is removably connected to the casing 1011 covering cable 1010. Cap 1012 can be removably connected to the casing 1011 using conventional means, such as a pressure fit, suturing, and the like.

As shown in Figs. 101B and 101C, cap 1012 can be disconnected from casing 1011 such that a tip 1013 of cable 1010 is exposed. In the embodiment shown in Fig. 101B, a pressure clip 1015 is removed from cap 1012. Tip 1013 can then be rotated using an instrument 1014, such as screwdriver or allen wrench, to turn cable 1010. Rotation of cable 1010 effects a change in the relative position of the heart-contacting surfaces of two or more main segment 10 bars, of some portions of main segments 10, and/or of the adjustable stabilizer/reconfiguration segment 12. Following adjustment of main segment 10 and/or adjustable stabilizer/reconfiguration segments 12, the cap 1012 can be reconnected to the casing, as shown in Fig. 101d. Fig. 101e illustrates an exemplary screw mechanism 1016 for rotating cable 1010 within casing 1011.

Fig. 102 illustrates another embodiment of an adjustment assembly of the present invention. The adjustment assembly illustrated in Fig. 102 includes a direct push-pull-driven linearly moving cable 1020 surrounded by a casing 1011. Cable 1020 illustrated in Fig. 102 can include a removable cap, such as the removable cap 1012 illustrated in Figs. 101A, 101B, 101C, 101D, and 101E. A push or pull movement of cable 1020 within casing 1011 causes a change in the relative position of the heart-contacting surfaces of two or more main segments 10, of some portion or portions of main segments 10, and/or of adjustable stabilizer/reconfiguration segments 12. The position of cable 1020 can be locked after adjustment by a set-screw, a knot, and the like



(not shown).

Fig. 103 illustrates another embodiment of an adjustment assembly of the present invention. Cable 1020 illustrated in Fig. 103 is similar to cable 1020 illustrated in Fig. 102, but is shaped to permit rotation by hand and without the use of an instrument.

5            Fig. 104 provides another embodiment of an adjustment assembly of the present invention. As shown in Fig. 104, cable 1020 can include a port 1040 for receiving a fluid. A needle 1041 may be inserted either percutaneously or after exposure through an incision for supplying and/or withdrawing fluid through port 1040 and into or out of cable 1020. If an incision is made, the needle 1041 and penetrable diaphragm may be replaced by a stopcock and  
10            mating tube-ends.

                 Another embodiment of an adjustment assembly of the present invention is illustrated in Figs. 105A and 105B. As shown in Figs. 105A and 105B, an electric or magnetic mechanism 1050 is driven by a transcutaneous coupling 1051. Fig. 105a shows an electrical transformer 1050 similar to the Transcutaneous Energy Transfer System (TETS) used for driving circulatory  
15            support. Fig. 105B shows a solenoid/permanent magnet 1052 driven by a hydraulic pump 1053. In one embodiment, replacement of the passive valves by magnetically reversible one-way valves would allow reversal of flow if desired. The relative spacing of main segment 10 and adjustable stabilizer/reconfiguration segment 10 can be adjusted by similar movement or electrical rotation of elements, for example, in any of Figs. 87, 88, 89, 90, 91A, 91B, 91C, 91D, 92A, 92B, 93A,  
20            93B, 94, 95, 96, 97, 98, 101A, 101B, 101C, 101D, 101E, using embodiments shown in Figs. 103, 104, 105A and 105B.

                 Main segment 10 and/or adjustable stabilizer/reconfiguration segments 12 of the present invention can include a movable inner surface 1060 that is positioned adjacent the heart, and an outer surface 1061 opposite movable inner surface 1060 that does not contact the heart. Figs.  
25            106a-113b illustrate embodiments of the invention for movement of an by inner (heart-contacting) surface 1060 of main segment 10 and/or adjustable stabilizing/reconfiguration segments 12 relative to an outer non-heart contacting surface 1061 of main segment 10.

                 Figs. 106A, 106B, and 106C illustrate an optional conforming jacket 1062 that can be employed in any of the mechanisms illustrated in Figs. 107-113B. The conforming jacket  
30            illustrated in Figs. 106A, 106B, and 106C is shown (a) cross-sectional view, (b) long sectional view, (c) perspective external view, respectively.

                 Fig. 107 illustrates a screw-operated pusher 1070 driven by a pull-cord 1071 for

movement of the inner (heart-contacting) surface 1060 relative to outer surface 1061. Fig. 108 illustrates a screw-operated pusher 1080 driven by a torque-cable 1081 for movement of the inner (heart-contacting) surface 1060 relative to outer surface 1061. Figs. 109A and 109B illustrate a screw-operated lever 1090 operated by a pull cord 1091 for movement of the inner (heart-contacting) surface 1060 relative to outer surface 1061.

Fig. 110A and 110B illustrate a screw-operated lever 1100 operated by a torque-cable 1101 for movement of the inner (heart-contacting) surface 1060 relative to outer surface 1061. When cable 1101 is rotated, threaded segments 1101 and 1103 cause levers 1100 to come toward each other which results in the separation of surfaces 1060 and 1061 as shown in Fig. 110b.

Figs. 111A and 111B illustrate a hydraulic bellows 1111 for movement of the inner (heart-contacting) surface 1060 relative to outer surface 1061. Figs. 112A and 112B illustrate a hydraulic piston 1121 for movement of the inner (heart-contacting) surface 1060 relative to outer surface 1061. In another embodiments inner surface 1060 is moved relative to outer surface 1061 via a direct hydraulic space 1122 between inner and outer surfaces 1060 and 1061, respectively is illustrated in Figs. 113A and 113B. Figs. 114A and 114B illustrate screw-approximating shims 1140 for movement of the inner (heart-contacting) surface 1060 relative to outer surface 1061. Here, shims 1140 are moved toward each other as the cable 1141 is rotated. This causes the separation of the inner (heart-contacting) surface 1060 relative to outer surface 1061.

As discussed above relative to Figs. 37A and 37B, the present invention can also include an apical cap (or bowl-shaped device) that fits over the outer (epicardial) surface of the apical part of the left ventricle for stabilizing devices adjacent heart 1. Such an apical cap may or may not extend onto the apical portion of the right ventricle. This aspect was discussed briefly above in regard to Figs. 37a and 37b which illustrate an embodiment of an apical coupling 370, such as a mounting block or cap, that fixes two or more reconfiguring bundles 320 of spring wires 321 together. Such an apical cap can also be used to stabilizing main segment 10 on the heart.

As shown in Fig. 115, apical cap 1150 (e.g., coupling 370 described with respect to Figs. 37A and 37B) has a shape and stiffness, particularly in the radial direction, which will not allow it to move substantially in any direction perpendicular to the long axis of the left ventricle. It provides, therefore, a stable anchoring member to prevent motion of a device on or in the heart surface, such as main segment 10 or bundle 320 of springs 321.

As shown in Figs. 115 and 116, apical cap 1150 is designed to fit adjacent the apical part

of the left ventricle. Two or more protrusions 1151 form a channel 1152 which is deep enough to receive main segment 10. Fig. 116 is a side view of apical cap 1150 shown in Fig. 115. In one embodiment, apical cap 1150 is made from a relatively soft material, preferably one having at least a durometer hardness Shore A of 60.

5           Figs. 117 and 118 show isometric views of apical cap 1150. Fig. 117 also shows two suture slots or holes 1171. Slots 1171 are used to suture the apical cap 1157 to the heart. Alternatively, or in addition to receiving sutures, slots 1171 can also perform the function of the coupling holes for receiving post tip 330 described above with respect to Fig. 37A.

10           Fig. 119 is a perspective view of another embodiment of an apical cap 1190. Apical cap 1190 is made of multiple (generally 12 or more) panels 1191 of soft biocompatible fabric which have been sewn or otherwise connected in the form of a "beanie." Panels 1191 are joined, in this particular drawing, at seams 1192. Seams 1192 perform the additional function of adding controllable stiffness in the radial direction, which prevents wadding or folding in the circumferential direction. Such wadding or folding is not desired because it would enable epical  
15           cap 1190 to slip laterally off the apical portion of the heart.

          Figs. 120A and 120B show apical cap 1190 with the addition of a soft polymer guide 1200 (e.g., channel) which facilitates position maintenance for a reconfiguration device such as that shown in Figs. 2B, 3, 14A, 14B, 53, 55, 63A, 63B, 64A, 64B, etc., including a main segment 10. Fig. 120B is a sectional view of the guide 1200.

20           Figs. 121A, 121B, 121C and 121D show more detail of the seam construction in Fig. 119. Fig. 121a illustrates a simple seam and Fig. 121b a section of that same seam. Fig. 121c is a buttressed seam incorporating a stiffening strip 1210 of additional fabric of felt or other stiffening material in a manner known to those skilled in the art of sewing, and Fig. 121d is a section of that shown in Fig. 121c.

25           Fig. 122 is a perspective view of an apical cap 1190 placed on a heart in accordance with one embodiment of this part of the invention.

          Fig. 123 is a side perspective view of the heart shown in Fig. 122, and also shows a pleat or tuck 1230 provided for circumferential size adjustment of apical cap 1190 using one or more sutures to adjust size.

30           Fig. 124 shows a main segment 10 of a heart remodeling device according to the present invention positioned on the heart, with main segment 10 positioned in guide 1200 of apical cap 1190.

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Fig. 125 illustrates apical cap 1190 with circumferential purse strings 1250 entered around one or more portions of apical cap 1180, that may be used to adjust the shape and size of apical cap 1190 as described with respect to Fig. 123. Four such purse strings are shown in Fig. 125, but any number may be used. As discussed with respect to Figs. 69A-72 above, apical cap 1190 may include pacing leads or transceiver elements such as those on main segment 10 or stabilizer/reconfiguration segment 12.

Fig. 126 shows an embodiment for releasably securing cable 481 as shown in Fig. 52, to main segment 10 having a center modular portion 1260, using a remote cable-clamping mechanism. Such a configuration is used to facilitate the general scheme of tether, cable, cord or wire-mounted clasp members by providing ease of placement and remote adjustability, while eliminating the reduction of positional stability inherent in long tethers, cables, cords, or wires disposed within sheaths. It should be noted that when the word "cable" is used, it is intended to be synonymous with the words, tether, cable, cord, wire, chain, strap, or other similar restraining device.

The general principle of this aspect of the invention is that of a cable-car clamp or a detachable ski-lift clamp. The resting position of the spring-activated clamp or brake is closed, so as to prevent cable movement. An active maneuver is required to effect spring release. Thus, the failure mode would presumably be loss of adjustability, as opposed to loss of cable stability.

In one embodiment, the mechanism is a fixation device located on a main segment 10, that can be released and adjusted remotely by an adjustment cable or other means. The clamp-releasing cable itself is different from the cable or tether that was described above with respect to Fig. 52 with regard to the clasp placement system and adjustment. When the cable clamp is released, transiently, by means of this alternate type of cable, the primary (clasp-supporting) cable may be adjusted in length. When the clamp is re-tightened, the primary cable length is again fixed.

In an embodiment shown in Fig. 126, a main segment 10 is shown with an apical cable 1261 partially exposed as it passes through apical segment 1262 of the spine of main segment 10. Sheath 1263 covers an atrial cable 1265 (not shown, but identical to apical cable 1261) and sheath 1264 covers apical cable 1261. It is the cables within sheaths 1263 and 1264 which can control the compression of main segment 10, as described in more detail below. Cables 1261 and 1265 may be the ends of one cable or two or more cables linked together, for example linked by one or more portions of main elements 10.

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Fig. 127 is an enlarged view of the center part of main segment 10 shown in Fig. 126. Fig. 127 shows the alignment of sheath 1264 for an atrial cable 1265, sheath 1263 for an apical cable 1261. Fig. 128A is a top view of that shown in Fig. 127. Fig. 128b is a longitudinal cross sectional view along line 128b-128b of a that shown in Fig. 128a.

5 Figs. 129-131 show the clamping mechanism comprised in the embodiments shown in Figs. 126-128b. Fig. 129 shows a clamping spring 1290 for clamping cables 1261 and 1265 to main segment 10. Fig. 130 shows a longitudinal section through the midline 130-130 of Fig. 129. Fig. 131 shows an enlargement of the threaded hole 1291 of Fig. 130.

Fig. 132 shows the clamping spring 1290 in position on center modular portion 1260. 10 Cables 1261 and 1265 which hold main segments to each other and on the heart are shown in place, running through modular center portion 1260. Clamp 1290, which houses clamp releasing cable 1320 is disposed within clamp releasing cable port 1322. More specifically, Fig. 132 shows a perspective view of an embodiment where the pressure and texture of the center cross-bar of the clamp 1290 imposes a generally normal force on cables 1261 and 1265 such that friction prevents 15 movement of the cables 1261 and 1265 unless a displacing tension in the cables is substantially greater than would arise from conceivable normal physiologic events.

Fig. 133 shows an enlarged view of the clamp releasing cable 1320 and clamp releasing port 1322. Here, torque is applied remotely to rotate clamp releasing cable 1320 which causes the threaded cable to advance into the clamp 1290, thereby progressively impinging on spine 20 segment 1265. This produces a bending outward of clamp 1290 so as to separate the clamp 1290 from spine segment 1265 sufficient to allow cables 1261 and 1265 to move. Cable 1261 and 1265 are resecured to main segment 10 by moving clamp releasing cable 1320 in an opposite direction allowing claim 1290 to reseat on cable 1261 and 1265.

An additional embodiment for releasably locking cables such as cables 1261 and 1265 to 25 main segment 10 is shown in Figs. 136, 137, 138, 139, 140, and 143.

Figs. 134-137 show side, perspective and isometric views of an alternative locking mechanism 1372. Control box 1370 is shown only to represent that a mechanism for control locking mechanism 1372 is attached thereto and required for releasing a clamp securing cable 1261 and 1265, and optionally, for increasing and decreasing the space between two main 30 segments 10. An umbilical-like connection 1371 connects control box 1370 with the locking mechanism 1372.

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Fig. 138 shows an enlarged view of a portion of locking mechanism 1372 showing purse string attachment points 1380, as discussed above with respect to a stabilizer/reconfiguration segment 12 in Figs. 7, 8, 10A and 10B.

Locking mechanism 1372 shown in Fig. 139 includes cables 1261 and 1265 which pass  
. 5 from umbilical-like connection 1371 into locking mechanism 1372, control cable 1390, spring 1393, and locking wedge 1392. In one embodiment, length of cables 1261 and 1265 is controlled through a ratcheted spool mechanism contained in a control box 1370.

The proximal end of the control cable 1390 is fixed to the control box and the distal end is fixed to the spring loaded locking wedge 1392. Locking mechanism 1372 is composed of locking  
10 wedge 1392 and spring 1393, as well as a wedging surface 1394, which is integral with the device frame. A wedging surface 1394 of locking wedge 1392 creates a pinch point for cables 1261 and 1265 between the wedging surface 1394 and a wedge 1400 itself. Wedge 1400 is spring loaded to insure the system will be locked when in the default position. The user can control the locking  
15 system through control cable 1390, which passes through umbilical sheath 1371. When the locking system is in the unlocked position, the cables 1261 and 1265 are be tightened or loosened thereby decreasing or increasing the space between two main segments 10. The control box controls cable length and cable tension.

In use, as control cable 1390 is rotated, spring 1393 is compressed and releases pressure on locking wedge 1392 which allows cables 1261 and 1265 to be tightened or loosened. To again  
20 secure cables 1261 and 1265 to wedging surface 1394, control cable 1390 is rotated in a opposite direction to decompress spring 1393.

Figs. 141 and 142 show an additional embodiment of the pad as described with respect to Fig. 55. Pad 550 has a hardness of 40 to 60 Shore A, and preferably is formed from a  
25 polyurethane rubber or implantable grade silicone. The longitudinal radius of curvature of pad 1430 as shown in Fig. 142 is designed to insure enough curvature to effect the desired shape change of a heart or chamber thereof. For example, the longitudinal radius of curvature of main segment 10 can range from convex to concave toward the heart and can be in the range of minus 120 mm to positive 120 mm.

The radius of curvature of the lateral edges of main segment 10 or plates 170 (as  
30 described above) have a radius of curvature in the range of 0.2 mm to 10 mm so the edges do not impact negatively on the heart surface.

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Fig. 143 shows an enlarged view of pad 1430 included in a main segment 10. Snap-on attachment 1432 holds pad 1430 on main segment 10. Grooves 1433 in main segment 10 allow about +/- 10 degrees of rotation in either direction (overall rotation of about 20 degrees) of the pad 1430. A plurality of grooves 1433 allows the user choices in actual attachment placement to improve the fit to the atrium and atrioventricular groove. Such a plurality should be sufficient to allow placement up or down about 1.5 to 2.5 mm (about 3 to 5 mm overall).

Additional embodiment of the present invention relates to spatial stabilization of a heart geometric remodeling device similar to those disclosed above with respect to Figs. 7-11B and 55-67. The addition stabilization, structures and uses thereof are described below.

In one embodiment, a strap or band extends from an anterior remodeling segment, in the region of the anterior atrioventricular junction, around the junction of the lateral free walls of the left atrium and left ventricle.

In a second embodiment, a strap or band similar to the above extends from an anterior remodeling segment around the remainder of the left atrium/left ventricular (LA/LV) junction anteriorly, around the entire junction of the right atrial and right ventricular free walls externally, and across the medial-most part of the posterior LA/LV junction to join a posterior remodeling segment. In one embodiment, in a first part of the path of the band or strap, the strap or band passes between the anterior aspects of the atrioventricular junction and the posterior aspects of the aortic and pulmonary artery roots.

A third embodiment relates to a circumferential strap or band placed, for example, around the root of the aorta above the level of the valve commissures and the supra-ventricular sinuses, and tethered to an anterior remodeling segment by a linear cord or band.

In all three of the above embodiments, minimally invasive placement techniques and remote (including video assisted) assembly are used.

Fig. 144 illustrates an embodiment showing a heart 1 having a device according to one aspect of the present invention. Heart 1 shown in this drawing has had the right atrial and ventricular free walls and the pulmonary artery removed. Fig. 144 shows a main segment 10 encircling a left ventricle 1441 connected via tether 1442 to aortic collar 1440 which surrounds artery 1443.

Fig. 145 illustrates the same configuration as that shown in Fig. 144 but without removal of the right atrial and ventricular free walls and pulmonary artery. Fig. 145 shows that tether 1442 passes between the aorta and the atrioventricular junctions, and that collar 1440 may lie

partially behind the right atrial appendage.

Fig. 146 shows a top view partial cross-section of the base of the heart with both atria and both aorta and pulmonic artery transected at their bases. Fig. 146 shows collar 1440 connected to tether 1442 which is in turn connected to main segment 10. Fig. 146 also provides a view of  
5 right ventricle 1460, mitral valve area 1461, tricuspid valve area 1462, aortic root 1463, and pulmonic root 1464.

Fig. 147 shows a heart with a first band 1470 passing around the right atrioventricular junction, and second band 1471 passing about the left atrioventricular junction, where first and second bands may be stabilizer/reconfiguration segment 12 as described for example in Fig. 5-8, or 68. Fig. 148 shows a top partial reduced cross-sectional view of the base of the view showing  
10 Fig. 147.

Figs. 149A and 149B show bands 1470 and 1471, respectively, off the heart. In one embodiment, section 1490 of band 1470 is the narrow region intended to pass through the transverse sinus behind the aorta. In one embodiment, bands 1470 and 1471 are made generally  
15 of a low-durometer medical polymer, with a cross-sectional contour molded to the general shape evident from the cut ends in Fig. 149b, as well as the cross section of stabilizer/reconfiguration segment 12 shown in Figs. 6 and 150. The material used to form the device according to the present invention, particularly the major components thereof, is similar to a closed-cell foam such as neoprene, in terms of transverse stiffness and longitudinal flexibility. A fabric reinforcement  
20 may also be used or included in this element of the device. Also, bands 1470 and 1471 may include transverse stays and/or drawstrings for shortening adjustment, such as that which is shown in Figs. 8, 10, 11A 11B.

Section 1490, which is intended to pass through the transverse pericardial sinus, is more nearly circular in cross section to match the anatomy in that location and to present a soft, blunt  
25 surface to underlie the right coronary artery. The overall width of band 1470 at their mid portion is generally about 10-30 mm, with a thickness of about 3 to 4 mm. Section 1490, in the area it passes through the coronary sinus is generally oval in cross section with a major axis of generally 8 to 10 mm and a minor axis of about 5 to 6 mm.

Band 1471 is shown in more detail in Fig. 149a. This band is generally similar the band  
30 1470 described above, except this band has a relatively consistent cross-section rather than a variable cross-sectional section 1490 present on band 1470.

Aortic collar 1440 is a cylindrical cuff collar of, for example either fabric, low-durometer



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polymer, or both (that is, fabric-reinforced polymer). The length or height (dimension parallel to the long axis of the aorta) is generally about 10 to 12 mm, and the thickness is generally in the range of 1 to 3 mm. Edges of collar 1440 are softly radiused (as discussed above with respect to main segment 19) to minimize tissue trauma. It either has a tether 1442 as described above as an  
5 integral part, or it as some other connection (suture tab, snap eyelet, etc.) point for such a part.

One example for placement of aortic collar 1440 would be to insert a band of polytetrafluoroethylene (PTFE) felt around the aorta, with ends sutured together. Movement of collar 1440 would include following dissection of the pericardial reflections and connective tissue between the aorta and pulmonary aorta, using a procedure commonly used by those familiar with  
10 the art of cardiac surgery in the process of achieving hemostasis after aortotomy closure. In this embodiment, fixation of a band onto collar 1440 would be achieved by sutures or staples, done by methods known to those skilled in the art. In one embodiment, if tether 1442 were to be an integral part with collar 1440, a single band of felt or other fabric longer than the aortic circumference would be passed around the aorta, and one end connected (e.g., sewn or stapled)  
15 end-to-side to the remaining part, with residual length forming tether 1442.

In another embodiment, a premolded cylindrical collar made of fabric-reinforced low durometer biomedical polymer such as silicone rubber or polyurethane is divided at one point in the circumference and fitted with hooks or snaps for reconnection after passage around the aorta.

In another embodiment, a hinged rigid or semi-rigid polymer or metal collar that has a  
20 snap-connect or other fastening mechanism familiar to those know to those skilled in the art of restoring circular configuration after circum-aortic placement.

Tether 1442 is a flexible band or cord, for example made of braided polyester, joining collar 1440 to a main segment 10. The connection mechanism to main segment 10 can be any of those familiar to those skilled in the art, including sutures, screws, rivets, hooks, and snaps.

Another aspect of the present invention relates to that discussed above with respect to Fig.  
25 69A. As noted above, Fig. 69A shows a cross-section in which main segment 10 is encased in a suturable material encasement 690 such as a polyester mesh, woven polyester, silicone rubber, polyester fabric or reinforced silicone. Encasement 690 about main segment 10 provides a means for attaching the straps 680 to main segment 10, which itself may be formed of material that  
30 would not accept a suture.

The present embodiment shown in Figs. 151-158 uses an sheath or jacket (e.g., an elastic sheath or jacket) surrounding at least part of the device to be fixed adjacent to the heart wall.

This aspect includes a method of locally fixing portions of a sheath or jacket to the epicardium, including fine sutures, adhesives, and mechanical fixation devices such as staples and clips, or combinations thereof.

Fig. 151 is a perspective view of a portion of a main segment 10 which is clad with an  
5 fabric sheath 1510 in accordance with the present embodiment. For this embodiment, stabilization protrusions 174 (such as shown in Figs. 77a, 77b, and 77c) extend through openings in the sheath 1510.

Fig. 152 is a perspective view of the device shown in Fig. 151, but from the outer (away  
from the heart) surface. Sheath 1510 is locally adhered (via form fitting or an adhesive or  
10 mechanical attachment) to the main segment 10 at discrete locations such as along parallel lines of attachment 1521. Segment 1520 is a backbone (e.g., a rigid rod) of main segment 10 that is to be attached to the heart in accordance with this embodiment, and pad 1522 is shown as covering segment 1520 to prevent segment 1520 from directly contacting the heart surface.

Fig. 153 is a cross section of the segment and sheath shown in Fig. 152. Stabilization  
15 protrusion 174 is shown in this view and is consistent with the disclosure above regarding delayed surface penetrating pegs shown in Figs. 76A-82B. Outer edges 1531 of sheath 1510 (at the pad margin) are fixable (e.g., by adhesive, sutures, staples, clips, rivets, etc.) to the epicardium. Pad 1522 can be attached at the region of sheath 1510 that crosses the outer part of pad 1522, or, preferably, include a seam or fold to present a more convenient region for suturing, adhering, or  
20 stapling of pad 1522 to the epicardium.

Fig. 154 shows a perspective view of the entire clasp according to one embodiment of the  
present application, including basal bridging section 1540 and apical bridging section 1541, both  
clad in a sheath 1510 consistent with the above disclosure, and two main segments 10. Sheath  
1510 in this embodiment covers posterior main segment 10 and the bridging sections, basal  
25 section 1540 and apical section 1541. Sheath 1510 also covers anteroapical and anteroapical  
junctions 1542 and 1543, respectively, which are junctions between the basal section 1540 and  
apical section 1541 and main segments 10. Sheath 1510 can be used to cover one or more desired  
portions of main segment 10 and/or basal bridging section 1540 or apical bridging section 1541.  
Also shown are adjustment strings or cables 22 (as discussed for example with respect to Fig. 7)  
30 exiting from the anterior main segment 10 within sheaths 1544.

Fig. 155 shows the embodiment of Fig. 154 except that a dense sheath 1510, such as one  
made from polyester mesh of expandable PTFE (e.g., porous or non-porous), is shown. The

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density of the fabric can be changed by varying the degree of openness of the weave or net or porosity of the material. Sheath 1510 can be a porous, non-porous, woven or non-woven material.

Fig. 156 is a cross section of main segment 10 according to one embodiment of the present invention, disposed on a heart surface 1 having sheath 1510 secured for example by suturing, adhesive, staples, clips, rivets, etc. at outer edges 1531, stabilization protrusion 174, and adhered to the main segment 10 at discrete locations such as along parallel lines of attachment 1521.

Fig. 157 is the same cross section as that shown in Fig. 156 and is offered to show the effect of a potentially displacing force from the left side (arrow 1570) of the device. Stabilization protrusion 174 is slightly displaced to one side of the epicardial indentation, and the point of fixation 1571 on the left is under tension.

Fig. 158 shows the same cross section as that shown in Fig. 156, after penetration of stabilization protrusion 174 into the myocardium and tissue ingrowth has occurred into the sheath 1510 (for example a porous or mesh sheath), both at the points of fixation 1580 (e.g., with sutures, staples, clips, etc.) and elsewhere in the region of the epicardial contact.

Another aspect of the present invention includes placement system for placing a heart clasp (including one or more main segments 10) such as that shown in Figs. 2A-4, including three components which collectively join to dilate a delivery passageway and allow the introduction of a treatment device system. The dilator itself is removed at the end of the insertion.

The first component is a dilator nose 1590 and is shown in Figs. 159 and 160. Dilator nose 1590 has two ends, a tip end 1591 and a connector end 1592 opposite tip end 1591. Dilator nose 1590 is circular in cross-section, has a center channel or opening 1593 approximately 1 to 2 mm in diameter, is made of a soft elastomer such as polyurethane, and has a spiral wire reinforcement to discourage kinking and maintain flexibility. Dilator nose 1590 is tapered from a tip-end diameter only slightly larger than the center channel, to a diameter of approximately 15 mm at its connector end 1592. In Fig. 159, dilator nose 1590 is connected to a second component, the dilator body 1594.

Fig. 160 shows dilator nose 1590 separated from dilator body 1594. Dilator body 1594 has a threaded connector end 1595, which can be seen in Fig. 160. Dilator nose 1590 has an approximately 6 mm-long inside-threaded connector 1596 at its connector end 1592. Construction of dilator body 1594 is the same as that described above for dilator nose 1590,

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namely dilator body 1594 is formed from a soft elastomer reinforced with spiral wire and having a center channel 1597. Dilator body is approximately 30 to 40 cm in length, and has two ends a body connector end 1598 and free end 1599 (seen in Fig. 159). Outside threaded connector 1595 has the same length as the inside threaded connector 1596 described above in regard to dilator nose 1590.

The third component is a dilator clasp adapter 1610 and is shown in Fig. 161A-161D. Dilator clasp adapter 1610 has two ends, a dilator body connecting end 1611 and a clasp connecting end 1612 (such as for connecting to one end of main segment 10). Dilator body connecting end 1611 is circular in cross-section with a diameter the same as that of the body, and it is equipped with a threaded connector identical to that of dilator nose 1590. Clasp connecting end 1612 has a cross-section and dimensions similar to the clasp segment to which it is to be attached (shown in Fig. 167). In one embodiment, clasp connecting end 1612 is generally flattened, and wider in the direction tangential to the heart than in the direction normal to the heart surface. Clasp connecting end 1612 has a projection 1612 that is elliptical in cross-section and tapered over its length. Projection 1612 is intended to fit into a corresponding mating socket in the clasp segment to which it is to attach, so that the clasp segment will not rotate on its long axis after attachment. As shown in Figs. 161C and 161D which are taken along lines C-C' and D-D', respectively, in Fig. 161A, dilator clasp adaptor 1610 includes a channel 1614 for accommodating a guidewire (not shown).

A method of using several devices according to the present invention is shown in Figs. 162-170. Fig. 162 shows a schematic representation of a heart located in a chest cavity. Fig. 162 shows that a small incision has been made into the subcutaneous tissue of the upper abdomen wall at point 1624, just below the lower rib margin, near the xiphoid process (that is, the or xiphisternum or the lowest part of the sternum or 'breast bone'). Then, using blunt and sharp dissection, the junction of the abdominal wall muscles and diaphragm is exposed and opened. Next, the pericardial sac is opened. The tip of a sterile flexible fiberoptic endoscope 1620, such as a bronchoscope, is introduced into the pericardial cavity, and, with visualization through the scope 1625, advanced behind the left ventricle 1621 and then behind the posterior wall of the left atrium 1622. Note that although Fig. 162 shows an eyepiece 1625 for illustration, the endoscope will typically be equipped instead with a video camera and image shown on a monitor as the surgeon advances the endoscope, allowing sterility to be maintained. Other structure shown is sternum 1623.

Fig. 163 shows a view as endoscope 1620 reaches the superior limits of the pericardial pouch called the 'oblique sinus'. The four pulmonary veins (1630, left inferior; 1631, left superior; 1632, right inferior; and 1633, right superior) flow into the posterior wall of the left atrium 1634). The inner surface posterior wall 1635 of the pericardial sac is also shown.

5            Fig. 164 shows a biting forceps 1640 of the type used for bronchial biopsies, advanced through the channel of endoscope 1641. The jaws of forceps 1640 are shown grasping pericardium 1635, cutting a hole 1642 in it. In this procedure, it is preferred to stay well away from the posterior wall of the left atrium 1634.

10            In Fig. 165, endoscope 1620 has been advanced through this hole, around the front of the left atrium and ventricle, and back out the entry site into the subcutaneous incision, all under direct vision through scope 1620. This guidance may or may not be aided with additional visualization, such as that provided by a thoracoscope via another port in the side of the chest, or x-ray fluoroscopy, both using methods familiar to those skilled in cardiac surgery. A forceps is then used to grasp an approximately 1-mm diameter tether or guide wire 1651 (which may be  
15            polymer cord, metallic cable, or similar flexible material as disclosed above) to pull this tether back around the path that had been negotiated by endoscope 1620.

Fig. 166 shows the dilator 1594 and 1590 (body and nose components) advanced over tether 1651.

20            In Fig. 167, dilator nose 1590 has been detached (unscrewed) from dilator body 1594, and dilator-clasp adaptor 1610 (as shown in Fig. 161) has been attached to the dilator body 1594. Tether 1651 end that passes through the connector is advanced through a tether-channel in the apical-posterior-basal portion of the main segment 10 and temporarily fixed at the opposite end of this portion. Traction on the dilator and the opposite end of the tether 1651 then pull main segment 10 between the posterior wall of the heart and the posterior wall of the pericardium.

25            Fig. 168 shows the apical-posterior-basal portion including a main segment 10 of the clasp in its intended position in back of the heart.

Fig. 169 shows tether 1651 being threaded into the superior end of the anterior portion of a second main segment 10 of the clasp, after dilator 1594 and dilator-clasp adaptor 1610 having been withdrawn from over tether 1651.

30            Fig. 170 shows the anterior portion including main segment 10 of the clasp with both ends of the tether 1651 threaded through its channels of main segment 10.

Fig. 171 shows the clasp including two main segments 10 in place, portions labeled as in Figs. 169 and 170, with the tether 1651 (optionally in outer sheaths 1711) in tether channels (no shown) on or in the clasp and extending into the subcutaneous incision. At this point, tether channels and tether 1651 ends may be connected to any adjusting and locking mechanisms  
5 discussed above, that are designed for use with the clasp in accordance with the present invention.

Another aspect of the present invention relates to that which is disclosed above with regard to clasp placement or fixation. In this embodiment, areas of hook and pile type Velcro® fasteners or similar reusable and removable fasteners, in a biocompatible material, are fixed, directly or indirectly as parts of a patch that is to be attached to the epicardium. Mating areas of  
10 hook and pile type Velcro® fasteners are part of a composite sheath within which the to-be-mounted structure is clad.

The type of Velcro® fastener selected (in terms of distribution) is such that the desired degree for freedom of placement and readjustment is obtained. Corresponding Velcro® fastener strips placed on the heart and the device may be parallel or perpendicular to one another.

15 Regions of Velcro® fasteners can include more elastic, fabrics of near equal thickness and thickness-compliance are combined so that lateral elasticity of these flexible composite structures is maintained. This is employed in construction of both the epicardial layer (containing hook and pile type Velcro® and more elastic fabric) and the sheath that is place about the to-be-mounted structure or structures.

20 More specifically, securing one side of the Velcro® fastener to the epicardium is generally done by multiple discrete fixation points, whether superficial (epicardium) sutures, rivets, cements, or very superficial staples, so as not to preclude segmental shortening or relaxation of the subepicardial myocardial layers. Securing other side of the Velcro® fastener to the to-be-mounted clasp segments (e.g., main segments 10) is similarly kept localized, generally on a  
25 surface not in contact with the heart (outer surface), along a single line perpendicular to the direction of maximal wall contraction (circumferential)—i.e., the center line of a vertical structure—or both.

A pattern of patch construction using 4-5 mm wide vertical (relative to the heart) strips of hook and pile type Velcro® fastener alternating with 5-7 mm wide strips of far more elastic  
30 polymer knit or weave, joined by flat stitching, and a similar sheath material, including alternating 3-4 mm wide Velcro® fastener and 4-5 mm wide elastic polymer in the structure sheaths, are non-limiting examples of such a system.

As an example, Fig. 172 shows a heart 1 with a composite patch including one side of Velcro® fastener and elastic polymer knit or weave is sewn to the surface of the heart. Strips of one side of a hook and pile type Velcro® fastener 1720 are adjacent but separated by interposed strips of elastic fabric 1721 having a thickness approximately equal to the strips of Velcro® fastener 1720.

Fig. 173 shows an enlarged view of a second side of a hook and pile type Velcro® strip which can be adhered to a heart contacting surface of a clasp bar (such as main segment 10) or other member to be attached to the heart. In one embodiment, this patch is comprised of interposed rows of strips of hook and pile type Velcro® fastener and strips of elastic fabric of similar thickness.

Fig. 174 illustrates a section of a heart wall and its attached structure interface where 1740 is the attached structure (such as main segment 10), 1741 is one layer of hook and pile type Velcro® fastener with interposed row of elastic fabric, and 1741 is the other layer of a hook and pile type Velcro® fastener with interposed rows of strips of elastic, and 1743 is the heart itself. Elastic strips allow some movement of Velcro® fastener longitudinally and laterally

The embodiment described above allows securing of prosthetic-tissue fixation without a precise determination of the final location of the prosthetic structure because a subsequent special determination can be decided after fixation of the Velcro® fastener containing epicardial strip. After that special determination is made, the structure can be removed, have its position altered, and replaced later in the operative procedure. In addition, this embodiment adds the benefits of (a) safe readjustment of position, and (b) more unobstructed, and thus likely safer, access to epicardial fixation points than that of either direct rigid-structure placement or attachment via a pre-mounted elastic sheath.

While the invention may be embodied in many different forms, there are shown in the drawings and described in detail herein specific preferred embodiments of the invention. The present disclosure is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

What is claimed is:

- 1                   1.     A device for treating a diseased heart, said device comprising:  
2                   one or more members configured to surround a selected portion of the heart,  
3                   including a first member configured to be positioned adjacent an exterior surface of one chamber  
4                   of the heart and to selectively deform the chamber by pressing inwardly thereon, and  
5                   a second member coupled to said first member, and configured (a) to lie adjacent  
6                   an external surface of the heart in a path forming an angle with said first member and (b) to  
7                   stabilize said first member on the heart.
- 1                   2.     A device according to claim 1, wherein said second member is a segment  
2                   configured to selectively deform a portion of the heart.
- 1                   3.     A device according to claim 1, wherein at least a portion of said second  
2                   member is a segment configured to lie adjacent the valvular annulus of the heart.
- 1                   4.     A device according to claim 1, wherein at least a portion of said second  
2                   member is configured to lie adjacent the papillary muscle of the heart.
- 1                   5.     A device according to claim 1, wherein at least a portion of said second  
2                   member is configured to lie adjacent the left ventricle of the heart.
- 1                   6.     A device according to claim 1, wherein at least a portion of said second  
2                   member is configured to lie adjacent the right ventricle of the heart.
- 1                   7.     A device according to claim 1, wherein said second member includes a porous  
2                   segment.
- 1                   8.     A device according to claim 1, wherein said second member includes a lattice  
2                   structure.
- 1                   9.     A device according to claim 1, wherein said second member includes a  
2                   segment configured to have an adjustable length.
- 1                   10.    A device according to claim 1, wherein said second member is rigid.
- 1                   11.    A device according to claim 1, wherein said second member is semi-rigid.  
2
- 1                   12.    A device according to claim 1, wherein said second member is flexible.



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- 1                   13. A device according to claim 1, wherein said second member includes a  
2 segment configured to be secured to a lumen of the heart.
- 1                   14. A device according to claim 1, wherein said first and second members are  
2 integral with one another.
- 1                   15. A device according to claim 1, wherein said second member is a protrusion.  
2
- 1                   16. A device according to claim 15, wherein said protrusion is a peg.
- 1                   17. A device according to claim 15, wherein said protrusion is blunt.
- 1                   18. A device according to claim 15, wherein said protrusion is resorbable.
- 1                   19. A device according to claim 15, wherein said protrusion is partially  
2 resorbable.
- 1                   20. A device according to claim 15, wherein said protrusion is non-resorbable.  
2
- 1                   21. A device according to claim 15, wherein said protrusion includes a non-  
2 resorbable porous element.
- 1                   22. A device according to claim 1, wherein said second member is a protrusion  
2 configured to penetrate a surface of the heart over a predetermined period of time.
- 1                   23. A device according to claim 1, wherein said second member is a protrusion  
2 configured to move relative to said first member and to a surface of the heart.
- 1                   24. A device for treating a diseased heart, said device comprising:  
2 one or more members configured to surround the heart, including  
3 a first member configured to be positioned adjacent an exterior surface of one  
4 chamber of the heart and configured to selectively deform the chamber by pressing inwardly  
5 thereon, and  
6 a second member configured to stabilize the first member of the device in a  
7 preselected position on the heart, said second member comprising a facing material on at least  
8 part of one side of at least one of said first and second members, and facing the exterior surface  
9 of the heart,

10                   said facing material being configured to facilitate epithelial growth into said facing  
11 material.

1                   25. A device according to claim 24, wherein said facing material is porous.

1                   26. A device according to claim 24, wherein said facing material includes a  
2 protrusion.

1                   27. A device according to claim 26, wherein said protrusion is a molded  
2 projection.

1                   28. A device according to claim 24, wherein said facing material includes a  
2 sheath configured to surround a portion of said first member.

1                   29. A device according to claim 28, wherein said sheath is porous.

1                   30. A device according to claim 28, wherein said sheath is elastic.

1                   31. A device according to claim 28, wherein said sheath is configured to be  
2 secured to an external surface of the heart.

1                   32. A device for treating a diseased heart, said device comprising:  
2 one or more members configured to surround a selected portion of the heart,  
3 including a first member configured to be positioned adjacent an exterior surface of one chamber  
4 of the heart and to selectively deform the chamber by pressing inwardly thereon, and  
5 a second member coupled to said first member, and configured (a) to lie adjacent  
6 an external surface of the heart in a path with said first member and (b) to stabilize said first  
7 member on the heart.

1                   33. A device according to claim 32, wherein said second member is configured  
2 to lie adjacent an apical portion of the heart and to accommodate a portion of said first member.  
3

1                   34. A device according to claim 33, wherein said second member is a conical.  
2

1                   35. A device according to claim 33, wherein said second member is configured  
2 to have an adjustable size.

1                   36. A device according to claim 33, wherein said second member includes at  
2 least one protrusion configured to accommodate a portion of said first member.

1 37. A device according to claim 36, wherein said protrusion is a channel.

1 38. A device according to claim 33, wherein said second member is rigid.

1 39. A device according to claim 33, wherein said second member is semi-rigid.

1 40. A device according to claim 33, wherein said second member is flexible.

1 41. A device for treating a diseased heart, said device comprising:

2 one or more members configured to surround the heart, including a first member  
3 configured to be positioned adjacent an exterior surface of one chamber of the heart and to  
4 selectively deform the chamber by pressing inwardly thereon, and

5 a second member configured to stabilize said first member of said device in a  
6 preselected position on the heart,

7 said second member comprising a first adherent surface on at least part of an  
8 inner side of said first member, facing the exterior surface of the heart.

1 42. A device according to claim 41, wherein said second member further  
2 includes a second adherent surface secured to an exterior surface of the heart for releasably  
3 attaching said first adherent surface.

1 43. A device according to claim 42, wherein one of said first and second  
2 adherent surfaces includes at least one hook and said other adherent surface includes uncut  
3 pile for releasably receiving the hook.

1 44. A device according to claim 42, wherein at least one of said first and second  
2 adherent surfaces is at least partially elastic.

1 45. A device according to claim 42, wherein said first adherent surface includes  
2 an adhesive.

1 46. A device for treating a diseased heart, said device comprising:

2 one or more members configured to surround the heart, including a first member  
3 configured to be positioned adjacent an exterior surface of one chamber of the heart and to  
4 selectively deform the chamber by pressing inwardly thereon, and

5 a second member configured to stabilize the first member of said device in a  
6 preselected position on the heart,

7                   said second member including one or more elements configured to penetrate an  
8 exterior surface of the heart.

1                   47. A device according to claim 46, wherein said second member includes  
2 protrusions configured to penetrate only an outer part of the exterior surface of the heart wall.

1                   48. A device according to claim 47, wherein said protrusions are configured to  
2 be retained within the heart wall.

1                   49. A device according to claim 46, wherein said second member includes  
2 protrusions configured to penetrate through the exterior surface of the heart wall and to be  
3 retained on an inside surface of the heart wall.

1                   50. A device for treating a diseased heart, said device comprising:  
2                   one or more members configured to surround the heart, including a first member  
3 configured to be positioned adjacent an exterior surface of one chamber of the heart and to  
4 selectively deform the chamber by pressing inwardly thereon, and  
5                   a second member configured to stabilize the first member of said device in a  
6 preselected position on the heart, said second member including one or more elements attached to  
7 said second member at spaced locations and configured to pass through the exterior surface of the  
8 heart.

1                   51. A device according to claim 50, wherein said elements are sutures.

1                   52. A device for treating a diseased heart, said device comprising:  
2                   a first member configured to contact a surface of a chamber of the heart and to  
3 continually bias a wall of the heart, and  
4                   a second member connected to said first member and configured to stabilize said  
5 first member in a preselected location in contact with the surface of the chamber.

1                   53. A device according to claim 52,  
2                   further comprising a third member connected to said first member and configured  
3 to be positioned on an exterior surface of the chamber and to selectively deform the chamber.

1                   54. A device according to claim 52, wherein said first member is a spring.

1                   55. A device according to claim 54, wherein said spring is a helical spring.

1                   56. A device according to claim 54, wherein said spring is a leaf spring.

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- 1                   57.    A device according to claim 54, wherein said spring is a coil spring.
- 1                   58.    A device according to claim 54, wherein said spring is a flat spring.
- 1                   59.    A device according to claim 52, wherein said first member is configured  
2 to lie inside a chamber of the heart.
- 1                   60.    A device according to claim 52, wherein said first member is configured  
2 to lie outside a chamber of the heart.
- 1                   61.    A device according to claim 52, wherein said first member is configured  
2 to lie inside a wall of a chamber of the heart.
- 1                   62.    A device according to claim 52,  
2 further comprising a biocompatible sheath covering a portion of said first  
3 member.
- 1                   63.    A device according to claim 52, wherein said second member is  
2 configured to lie adjacent an apical portion of the heart and to accommodate a portion of said first  
3 member.
- 1                   64.    A device according to claim 1,  
2 further comprising a transceiver coupled to one of said first member and said  
3 second member for receiving and transmitting electronic signals to and from said device.
- 1                   65.    A device according to claim 1, wherein said first member includes a  
2 plurality of elements pivotally connected to said first member, wherein said elements are  
3 configured to maintain a tangent position on a surface of the heart.
- 1                   66.    A device according to claim 65, wherein said elements are rigid.
- 1                   67.    A device according to claim 65, wherein said elements are semi-rigid.
- 1                   68.    A device according to claim 65, wherein said elements are flexible.
- 1                   69.    A device according to claim 65, wherein said elements have an edge and  
2 said edge has a radius of curvature of between 0.2 mm and 10 mm.
- 1                   70.    A method for placing on a diseased heart a device including a tether  
2 having two ends, said method comprising the steps:  
3                   passing the tether along a predetermined line of approximate placement position  
4 on the heart of the device,

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5           attaching a first portion of the device to one end of the tether,  
6           pulling a first portion of the device into approximate placement position with the  
7 tether,  
8           attaching a second portion of the device to the second end of the tether,  
9           sliding the second portion along the tether and placing the second portion of the  
10 device into approximate placement position abutting said first portion, and  
11           connecting the two portions to one another.

1           71.    A method according to claim 70, further comprising the step of passing  
2 the tether and a portion of the device through an opening in a pericardial reflection of the heart.

1           72.    A method for placing on a diseased heart a device including a tether  
2 having two ends, said method comprising the steps:

3                   passing a tether having two ends along a predetermined line of approximate  
4 placement on the heart of the device,

5                   sliding a sheath over the tether,

6                   attaching one end of the sheath and one end of the tether to a first portion of the  
7 device,

8                   pulling the first portion of the device into approximate placement position on the  
9 heart,

10                  disconnecting the sheath and sliding the sheath off the tether,

11                  attaching a second portion of the device to the tether,

12                  sliding the second portion along the tether and placing the second portion of the  
13 device into approximate placement position, and

14                  connecting the two portions to one another.

1           73.    A method according to claim 72, further comprising the step of passing  
2 the tether, sheath and a portion of the device through an opening in a pericardial reflection of the  
3 heart.

1           74.    A method for placing a device in a diseased heart, the device including a  
2 first automatically reversibly collapsible anchor and a first tether attached thereto, and a second

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3 automatically reversibly collapsible anchor and a second tether attached thereto, said method  
4 comprising the steps:

5                   passing a sheath through a lumen into an interior portion of a chamber of the  
6 heart,

7                   sliding the first collapsible portion in a collapsed position through the sheath and  
8 through a first predetermined portion of a wall of the chamber and causing the first collapsible  
9 anchor to expand,

10                   sliding the second collapsible portion in a collapsed position through the sheath  
11 and through a second predetermined portion of a wall of the chamber and causing the second  
12 collapsible anchor to expand, and

13                   connecting a free end of the first tether to a free end of the second tether.

1                   75. A method for placing on a heart a device for encircling the heart and for  
2 pressing inwardly thereon, the device included a plurality of elongate elements adapted to be  
3 joined successively with one another and, when joined, to surround the heart, said method  
4 comprising the steps:

5                   placing a guide member in a path around the heart, the path corresponding  
6 generally to a pre-selected location surrounding the heart in which the joined elongate elements  
7 are intended to be located,

8                   guiding one or more of the elongate members along the guide member to the  
9 preselected locations of each of the elongate elements on the heart, and

10                   after two of the elongate members are in their respective pre-selected positions,  
11 joining the two elongate members together.

1                   76. A method according to claim 75, wherein the guide member is a tether  
2 configured to pull the elongate elements along the path.

1                   77. A method according to claim 75, wherein the guide member is a tubular  
2 member configured to pull the elongate elements along the path.

1                   78. A method for introducing a transventricular tension member between  
2 substantially opposing walls of a heart chamber and anchor members on each end thereof, the  
3 anchor members being expandable from a compressed configuration in which the anchor is  
4 confined to a relatively small diameter to an expanded configuration in which one end of the

- 79 -

5 anchor is expanded to a relatively larger diameter including a relatively planar surface, and the  
6 anchor member is attachable to a tension member extending away therefrom, said method  
7 comprising the steps:

8 endoluminally introducing a first anchor into an interior of the chamber in the  
9 compressed configuration and causing the first anchor to pass through a wall of the chamber to  
10 the exterior thereof,

11 causing the first anchor to expand to its expanded configuration with the planar  
12 surface resting against an exterior surface of the chamber wall,

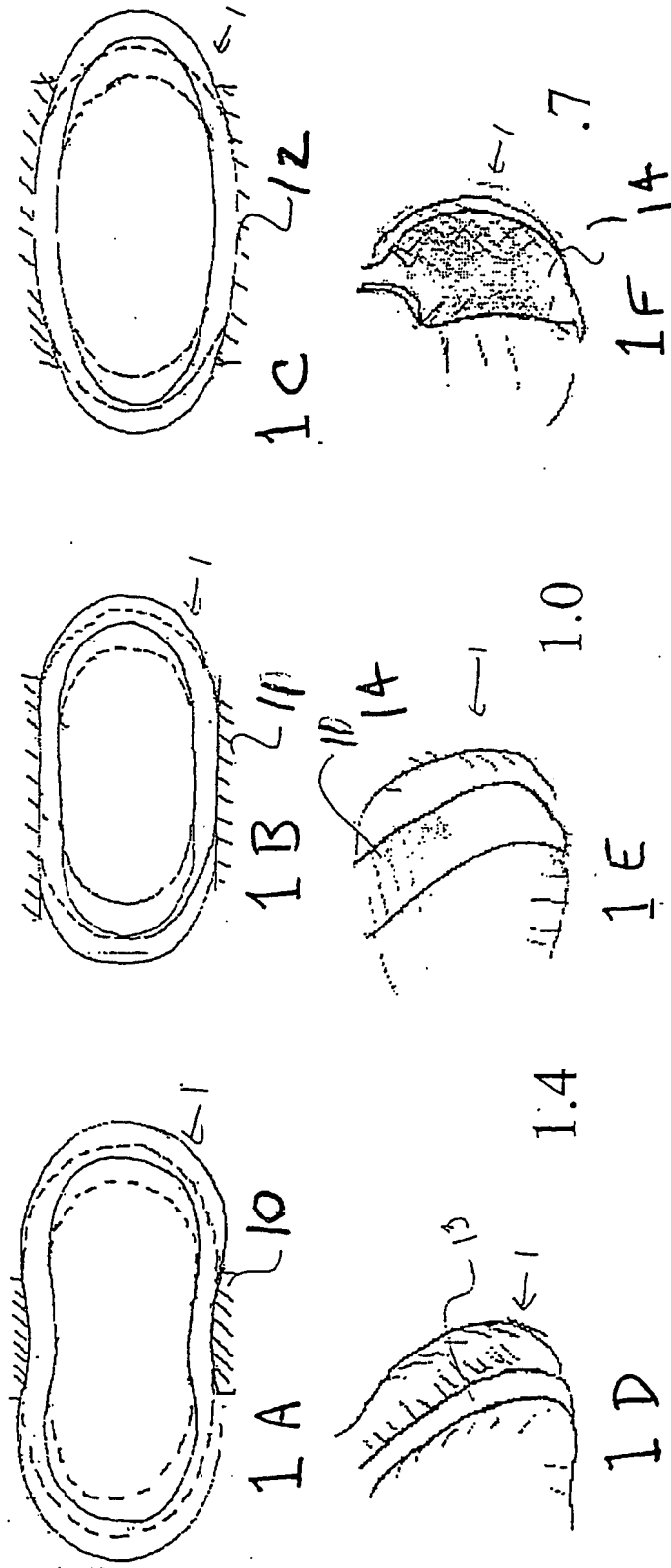
13 endoluminally introducing a second anchor into an interior of the chamber in a  
14 compressed configuration and causing the second anchor to pass through a wall of the chamber to  
15 the exterior thereof,

16 causing the second anchor to expand to its expanded configuration with the planar  
17 surface resting against an exterior surface of the chamber wall, and

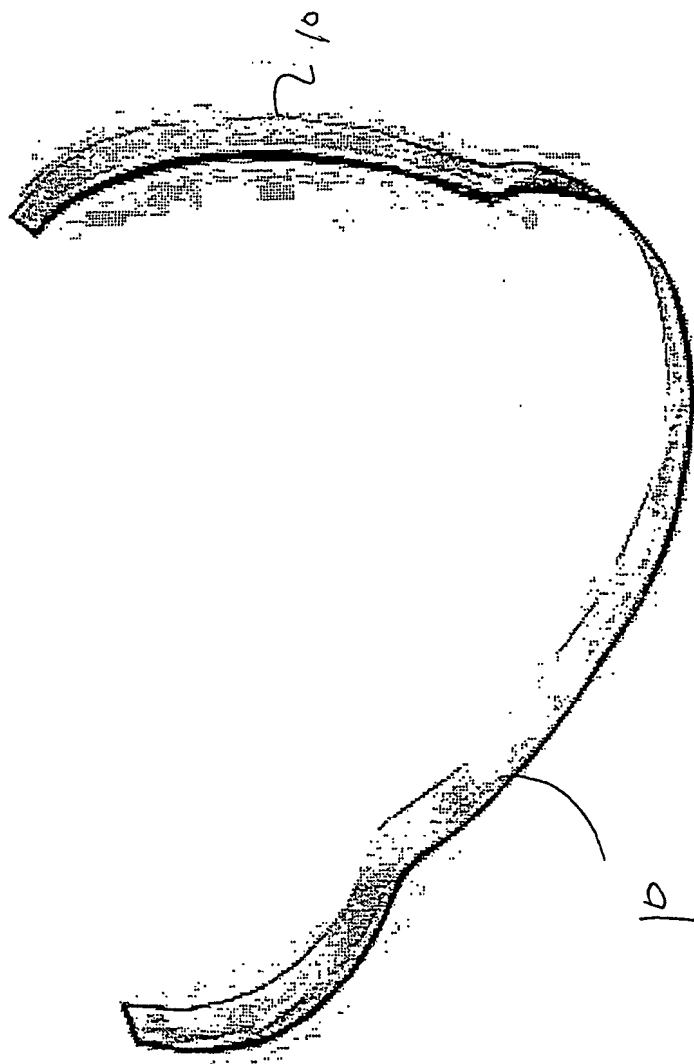
18 connecting the first and second anchors to a tension member.



Figure 1



(Fig. 2A)



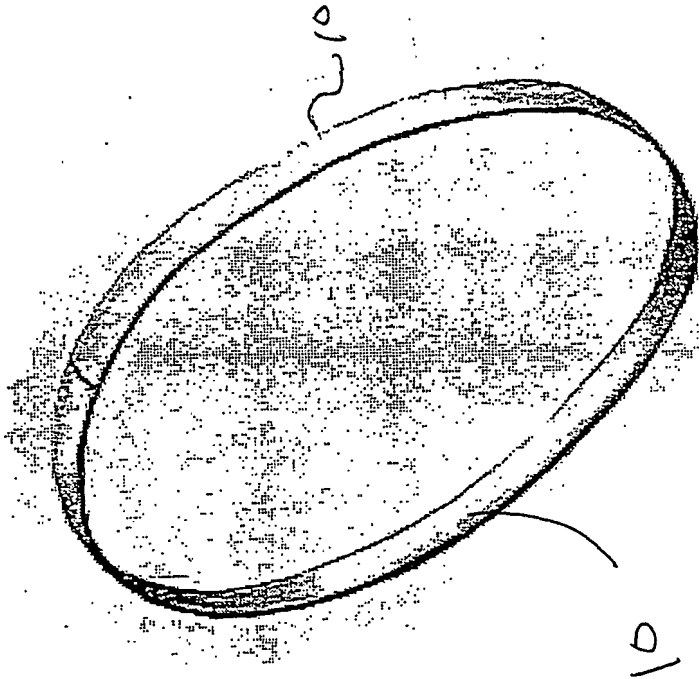


Fig. 10  
2B

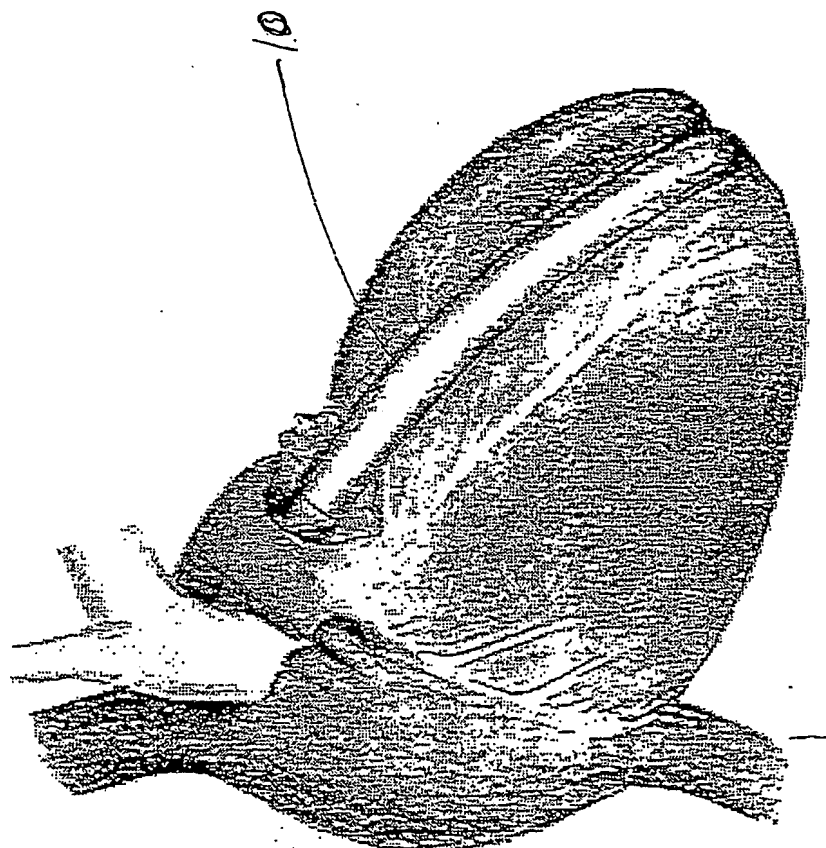
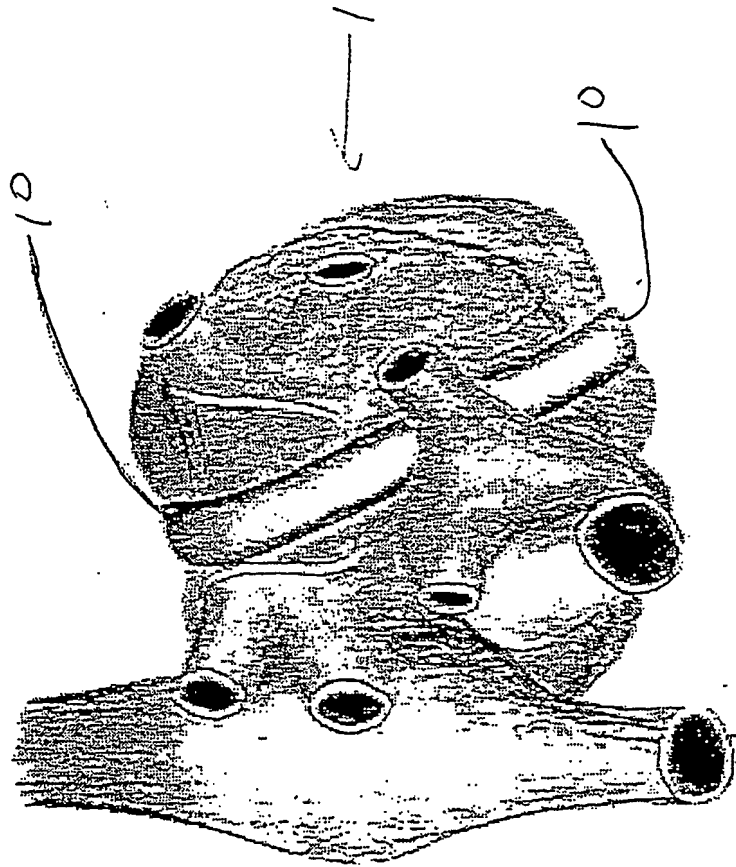
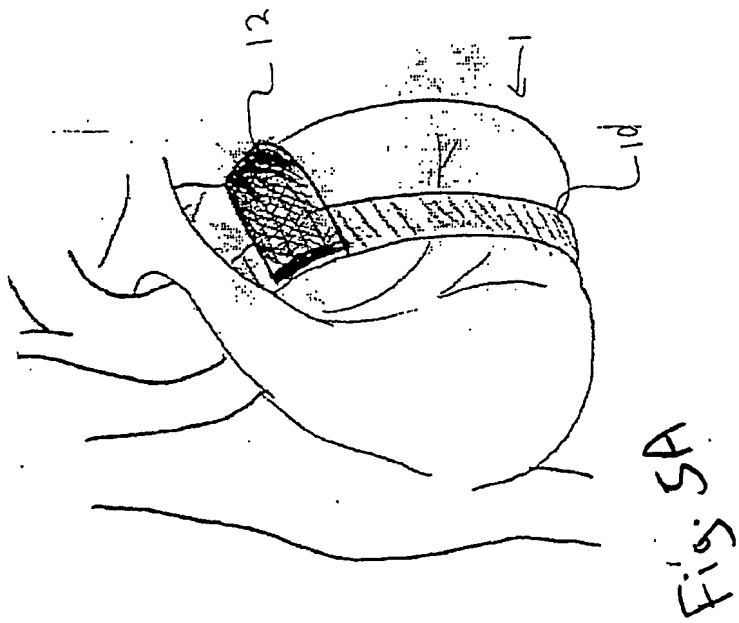
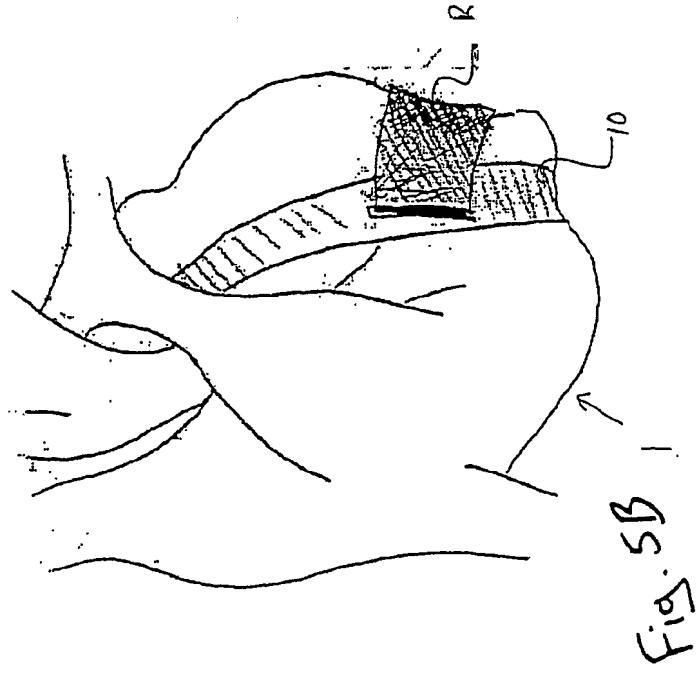


Fig.  
3



4  
Fig.



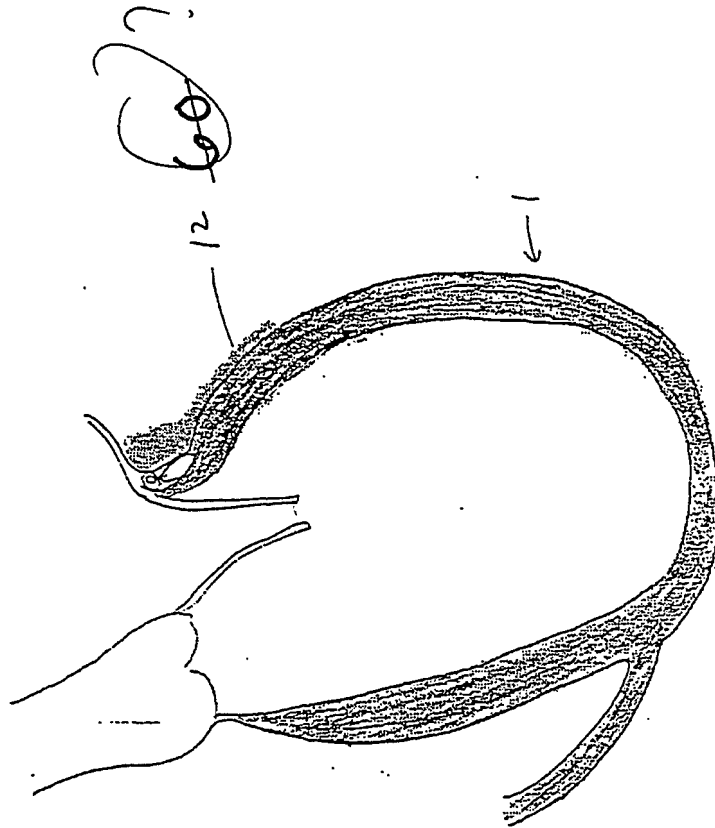


Figure 6

Fig. 7

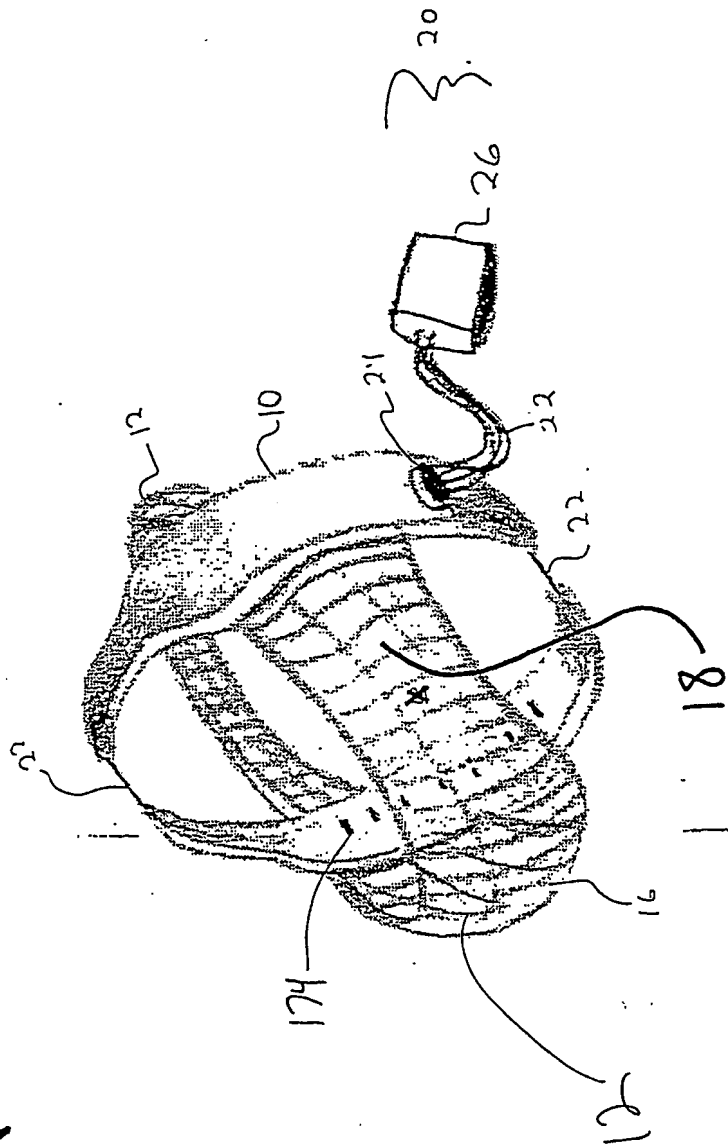
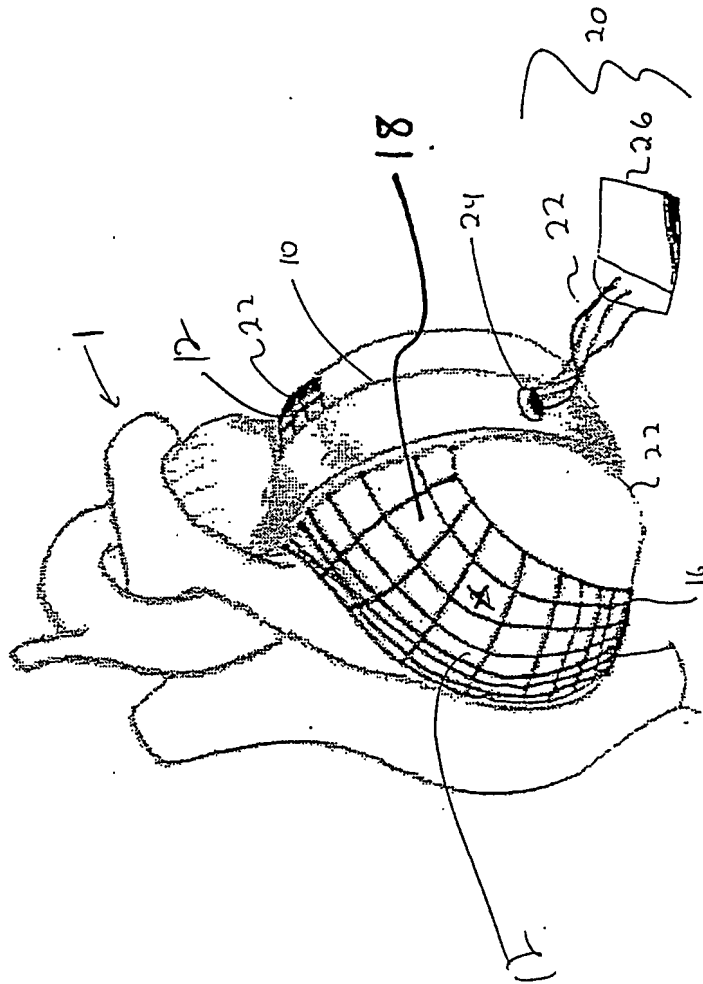




Fig. 8



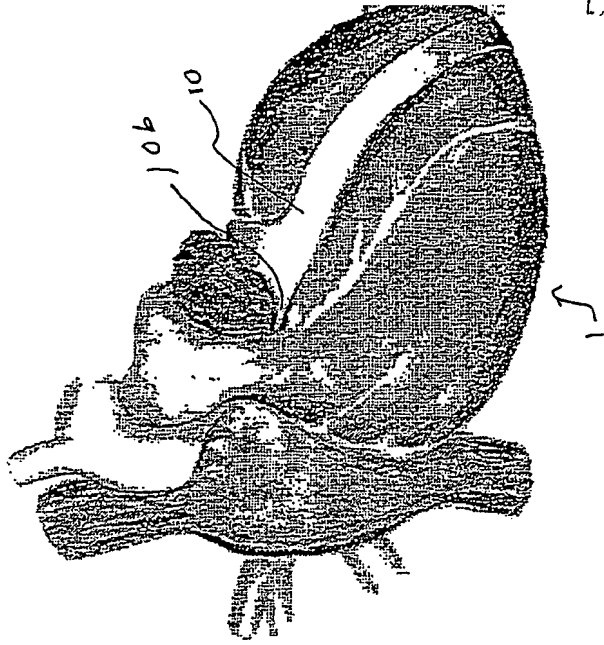


Fig. 9B

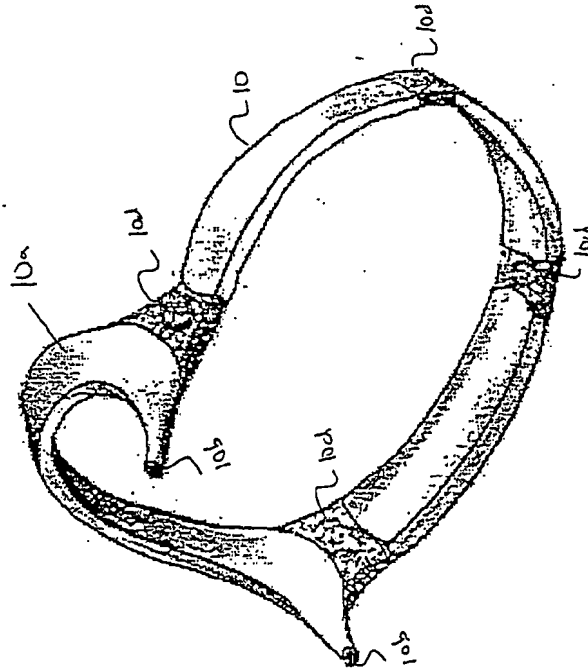


Fig. 9A

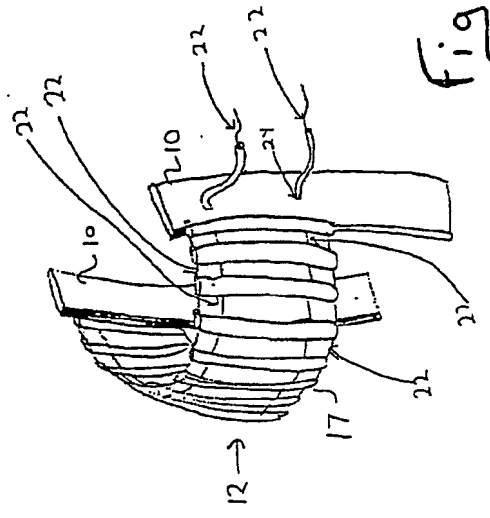


Fig. 10B

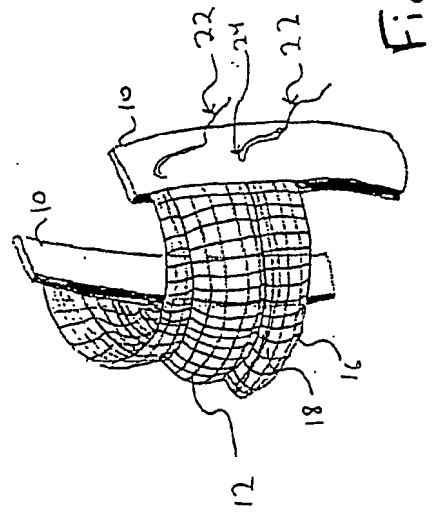
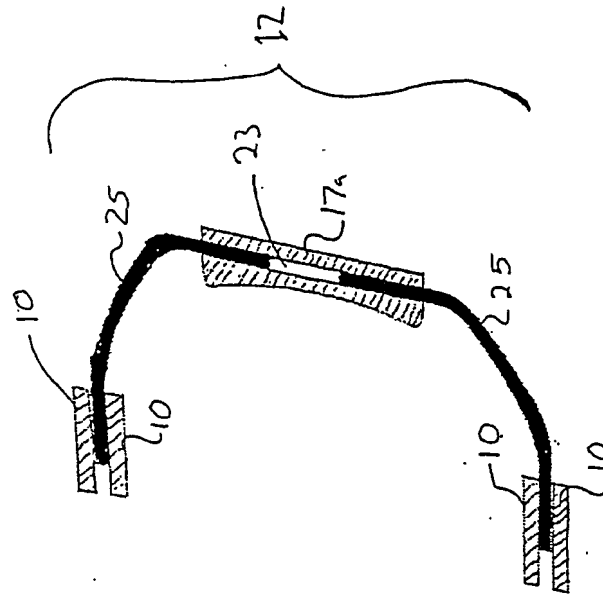
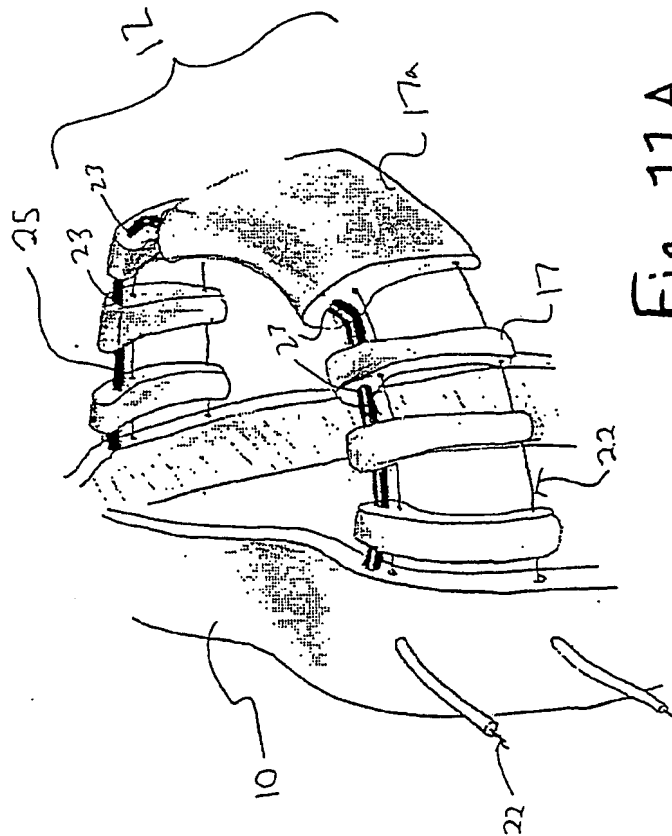


Fig. 10A



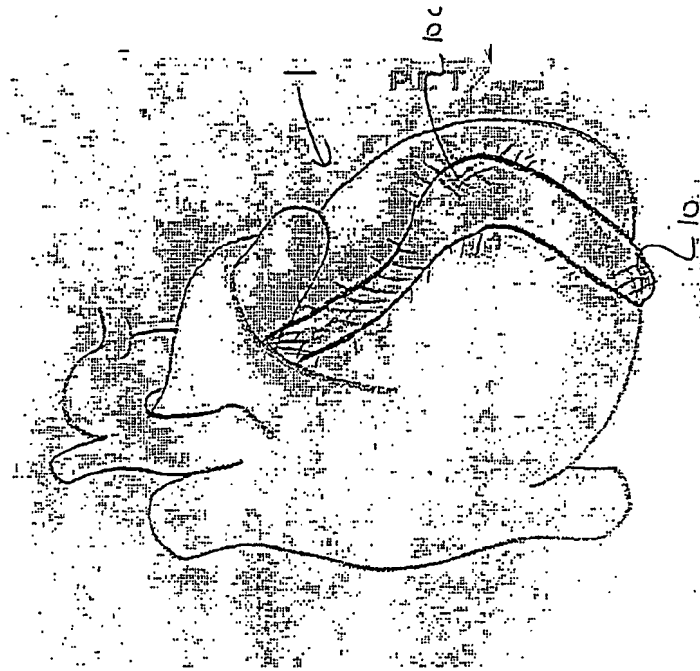


Fig. 12B

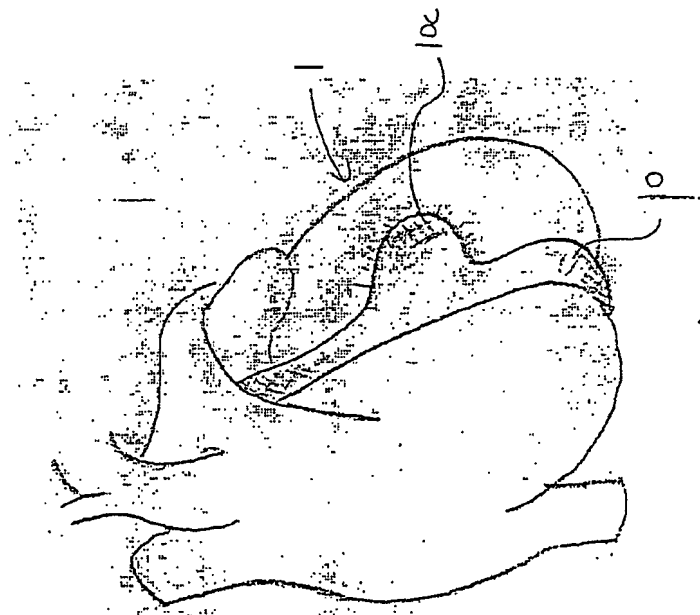


Fig. 12A

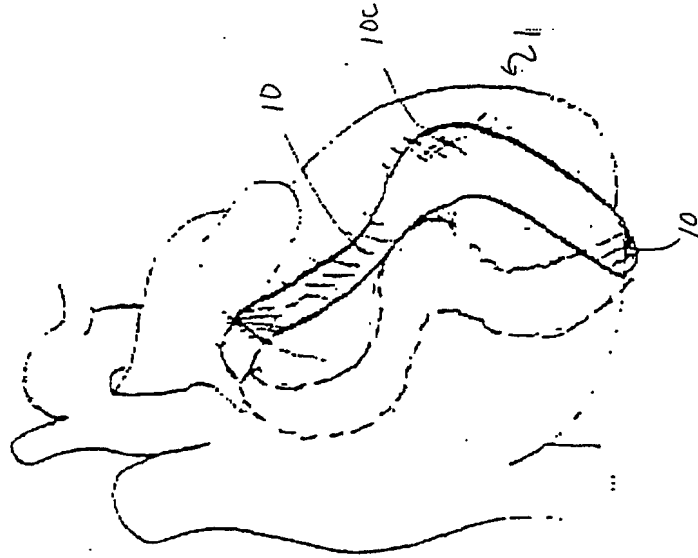


Fig. 13A

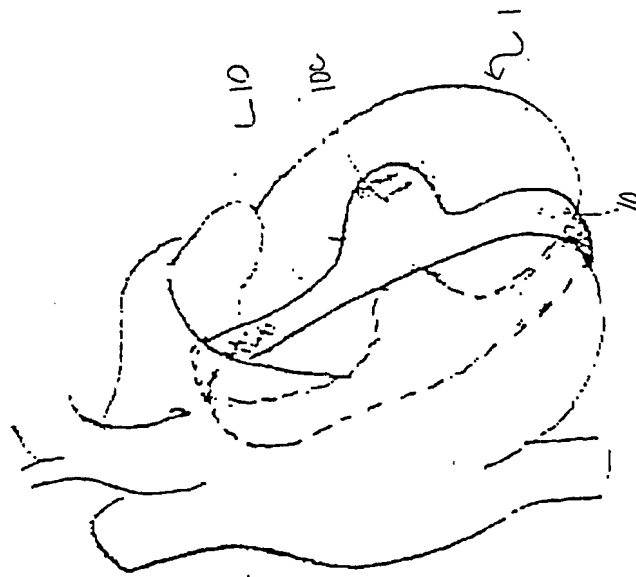


Fig. 13B

Fig. 13

Fig. 14

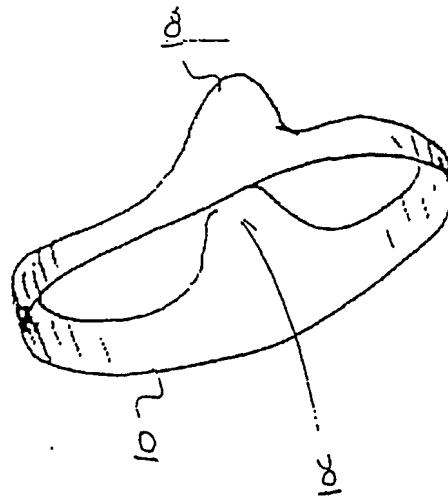


Fig. 14A

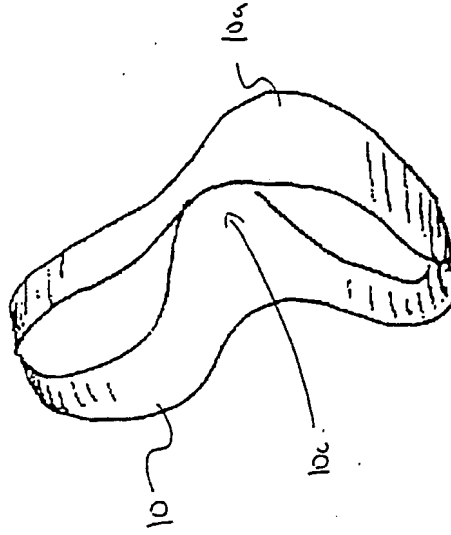


Fig. 14B

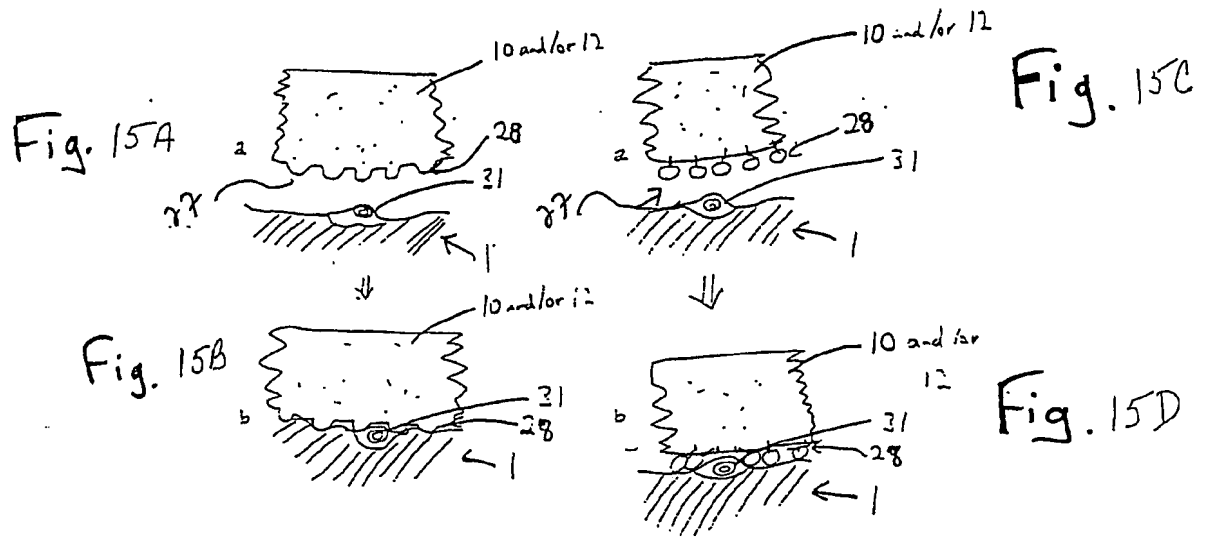
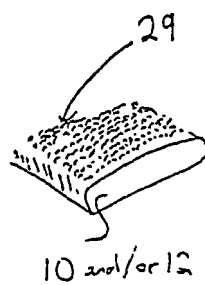
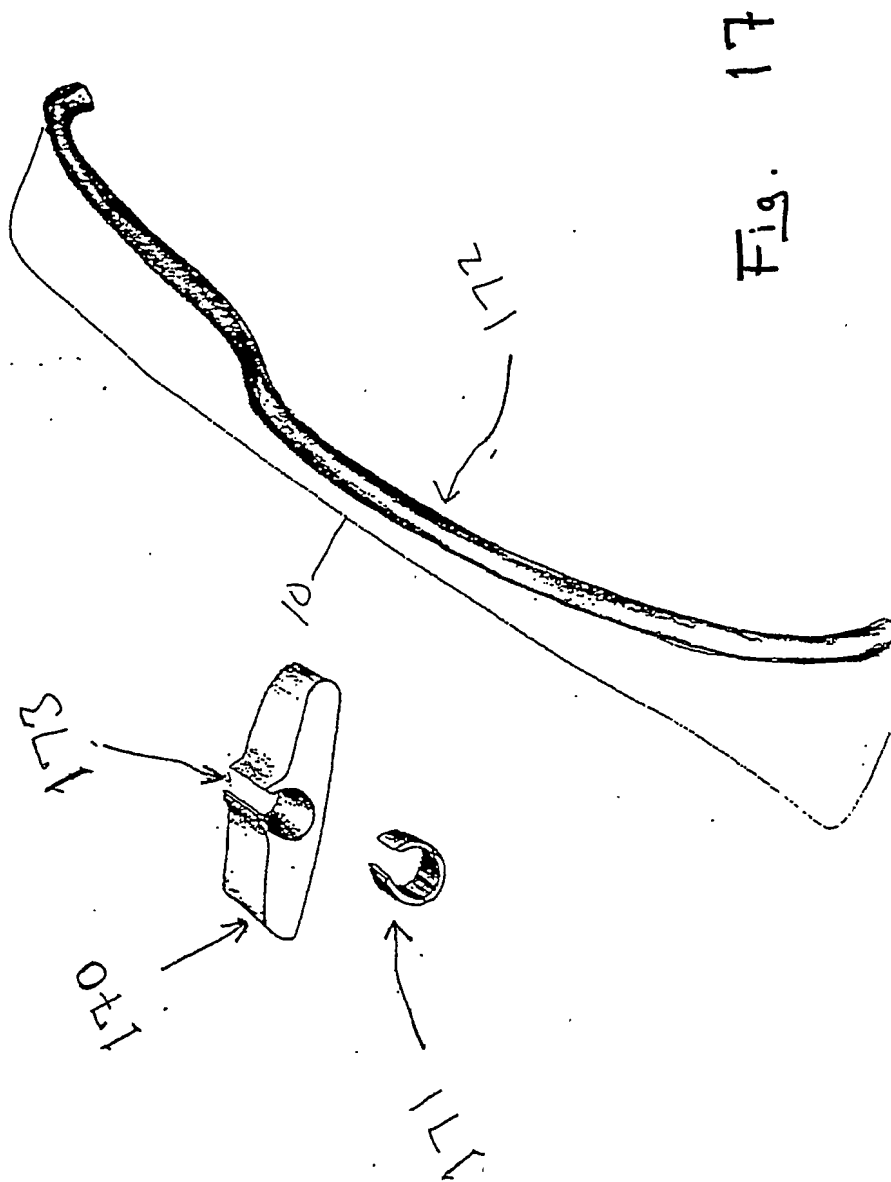
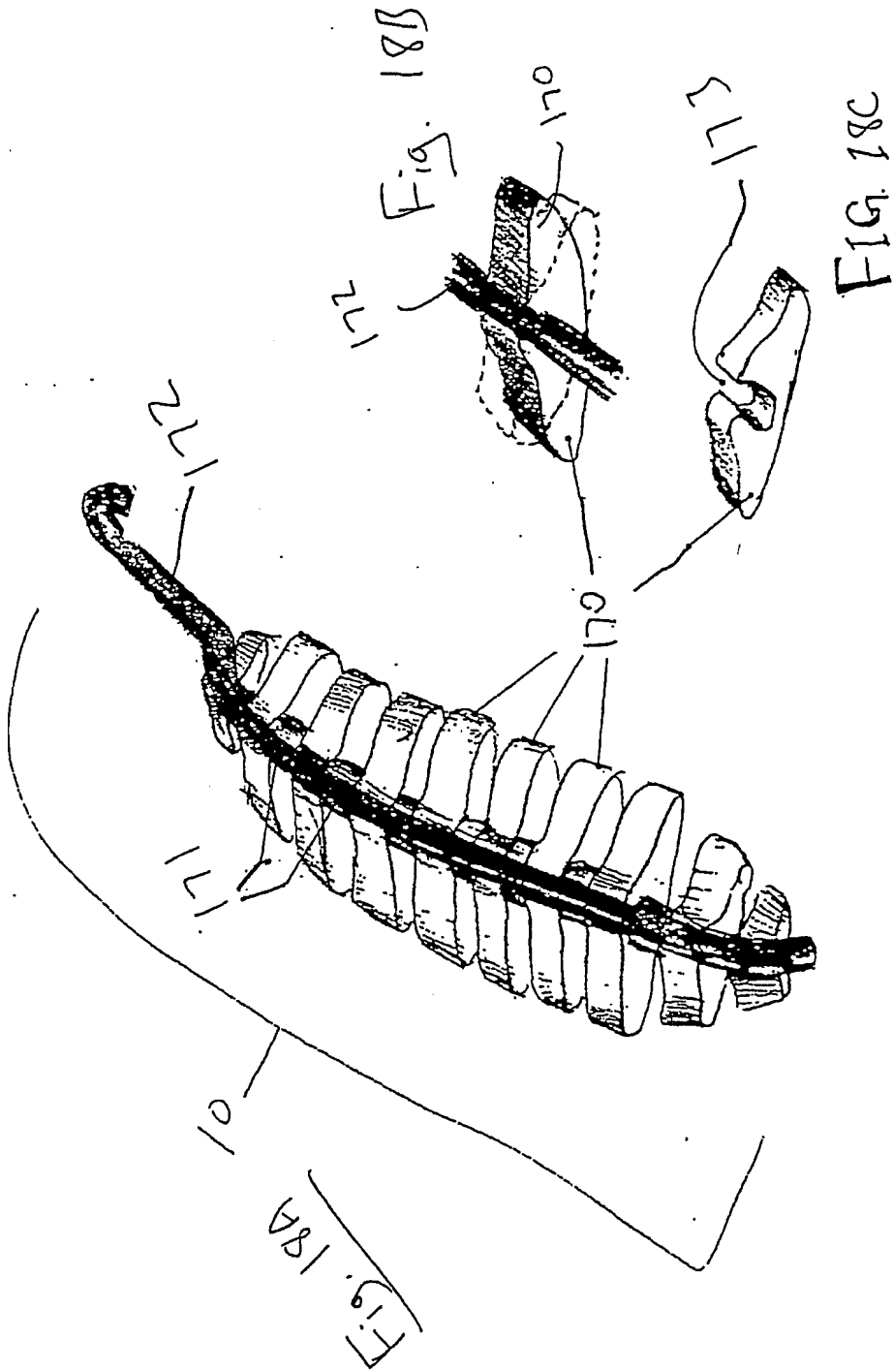




Fig. 16







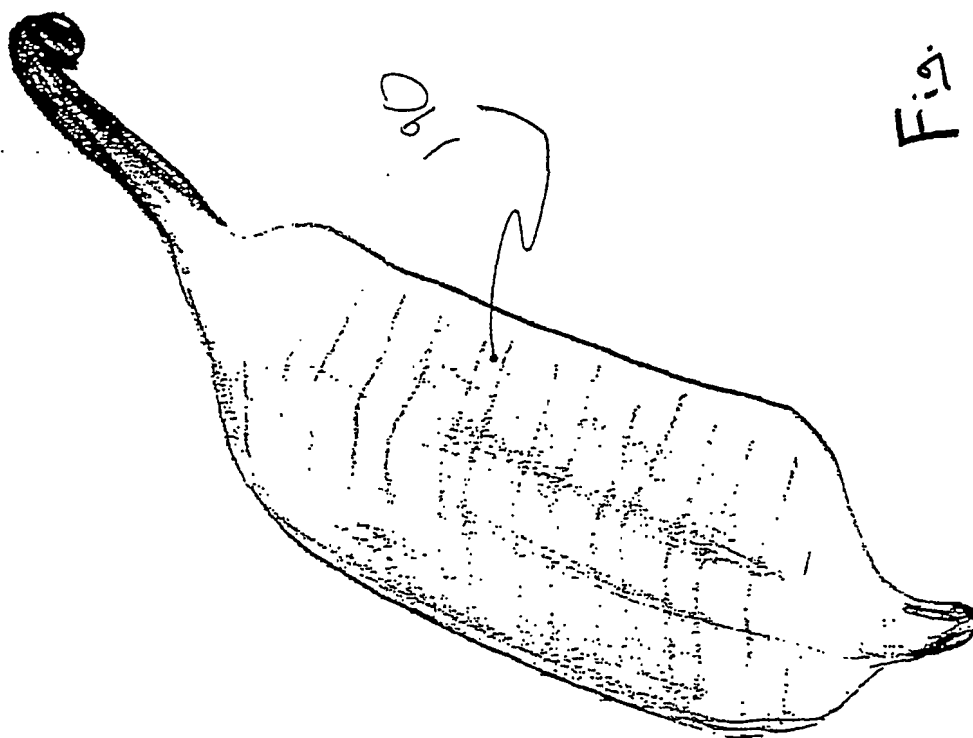


Fig. 19

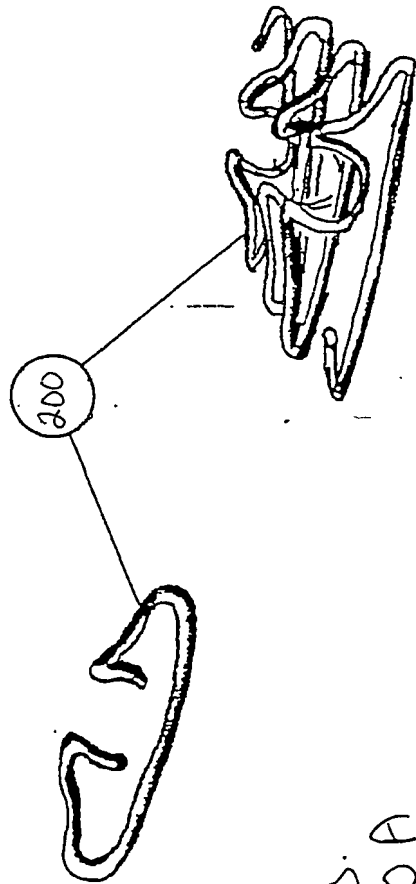


Fig.  
20A

Fig. 20B

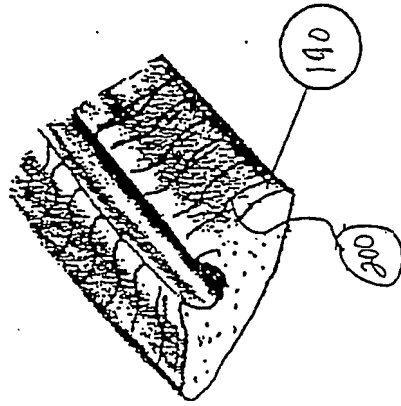


Fig.  
20C

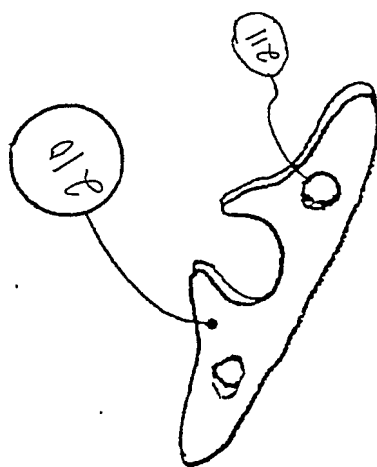


FIG. 21A

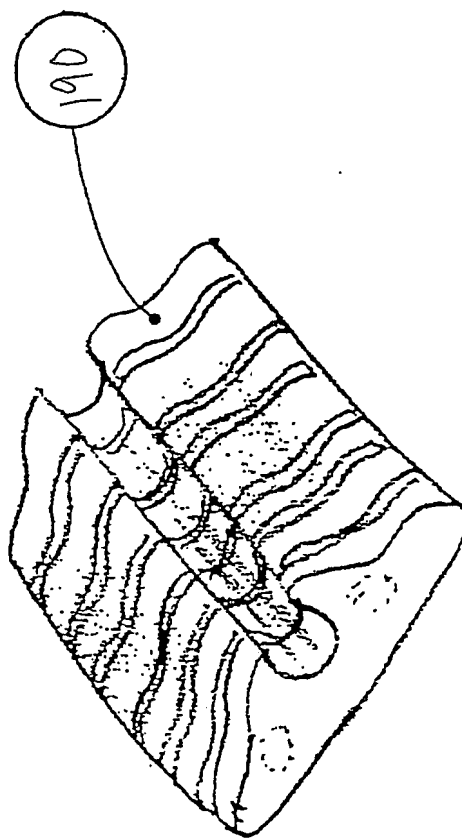


FIG. 21B

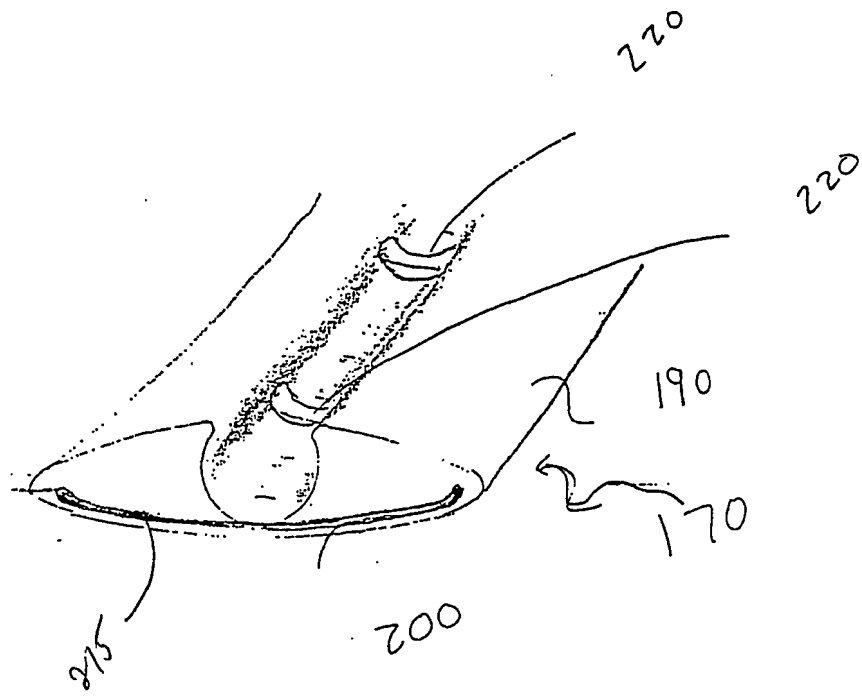


Fig. 22

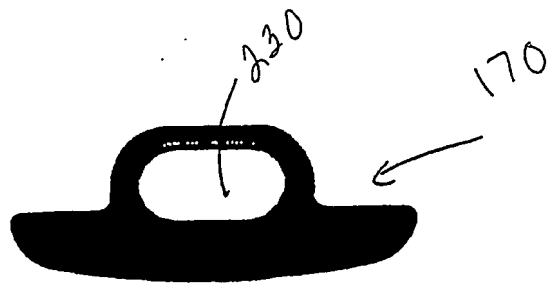


Fig. 23



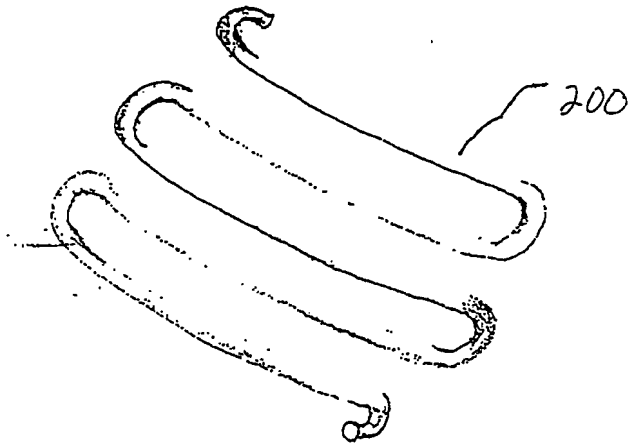


Fig. 24

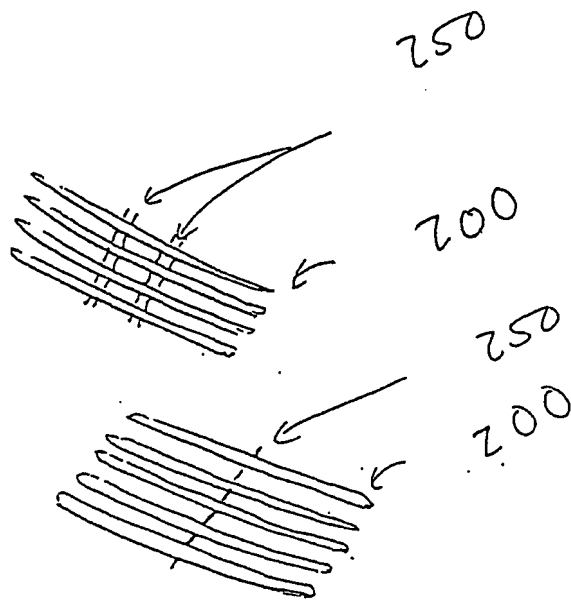


Fig. 25

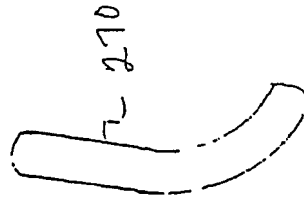


Fig. 27

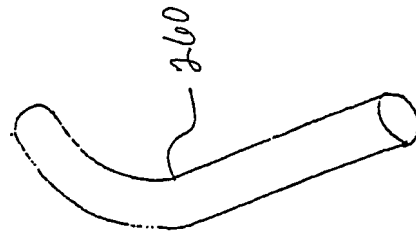


Fig. 26

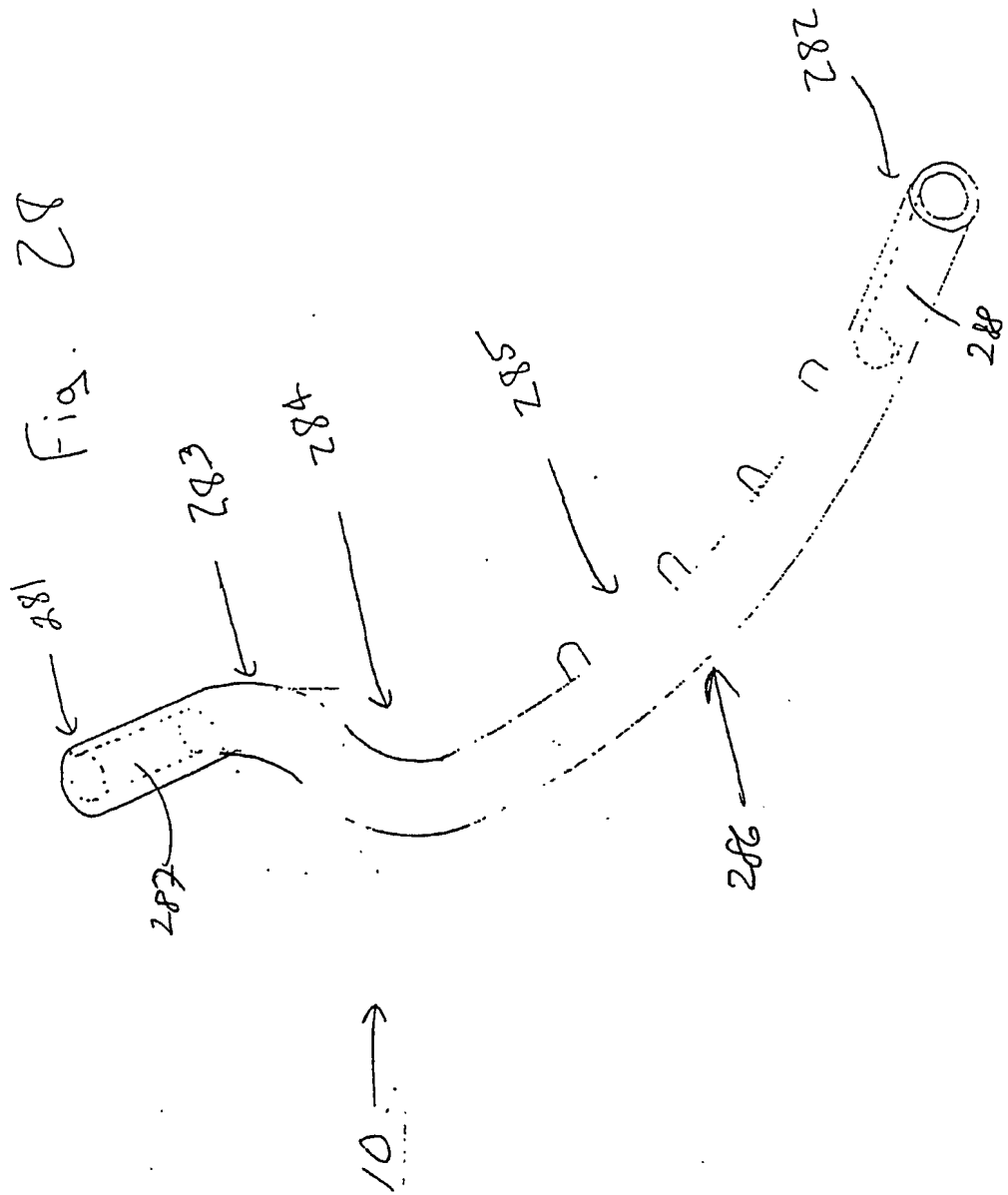




Fig. 30

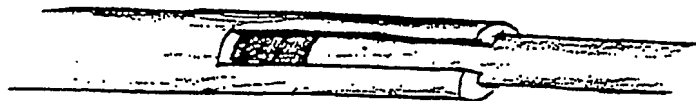
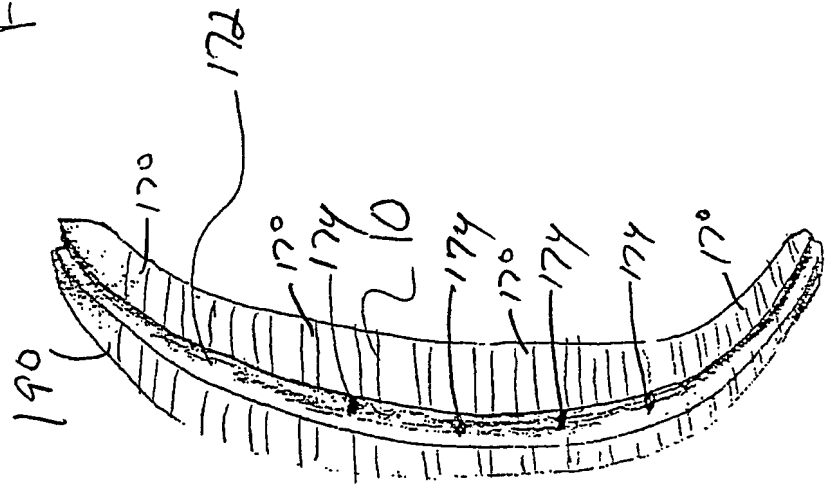


Fig. 29

Fig. 31



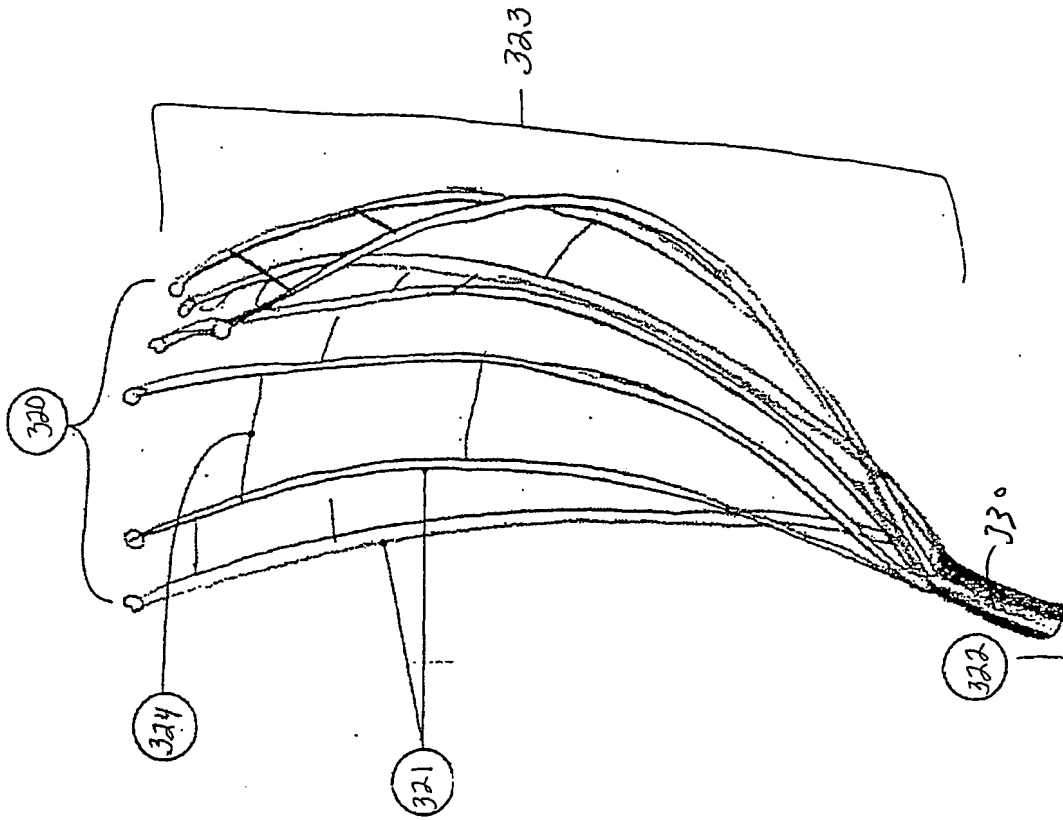


Fig. 32

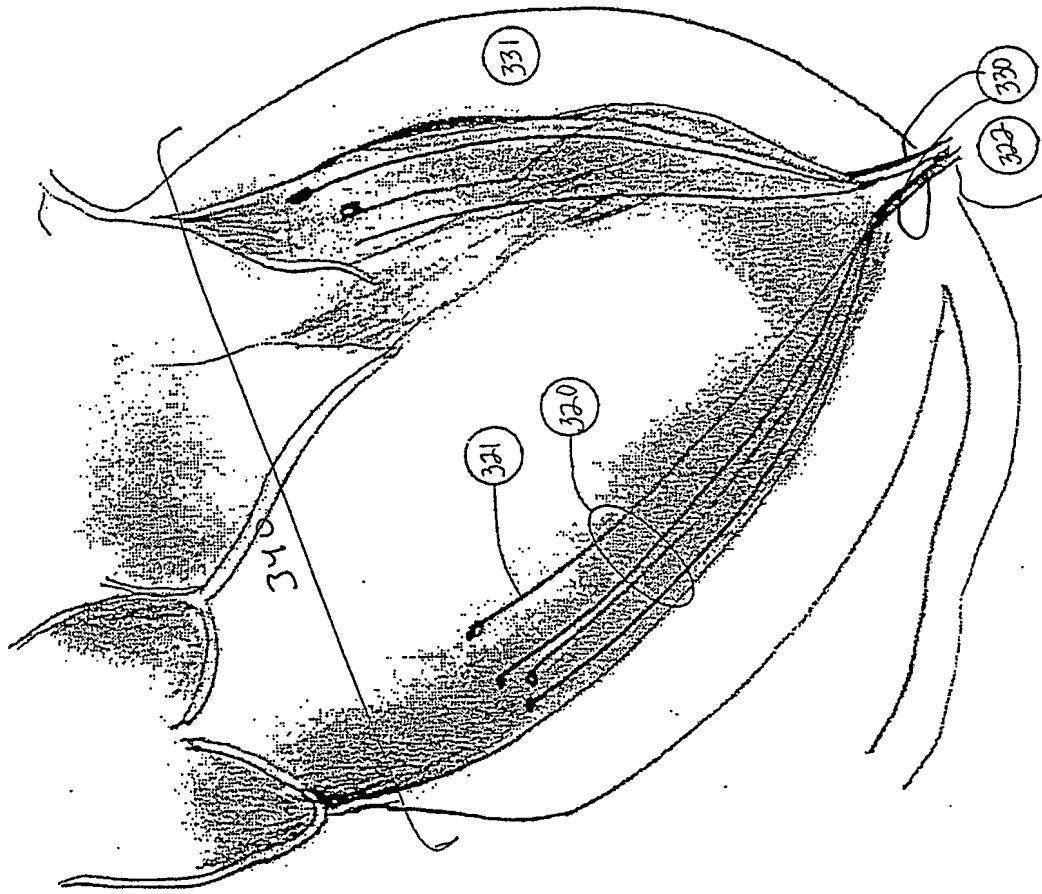


Fig. 3



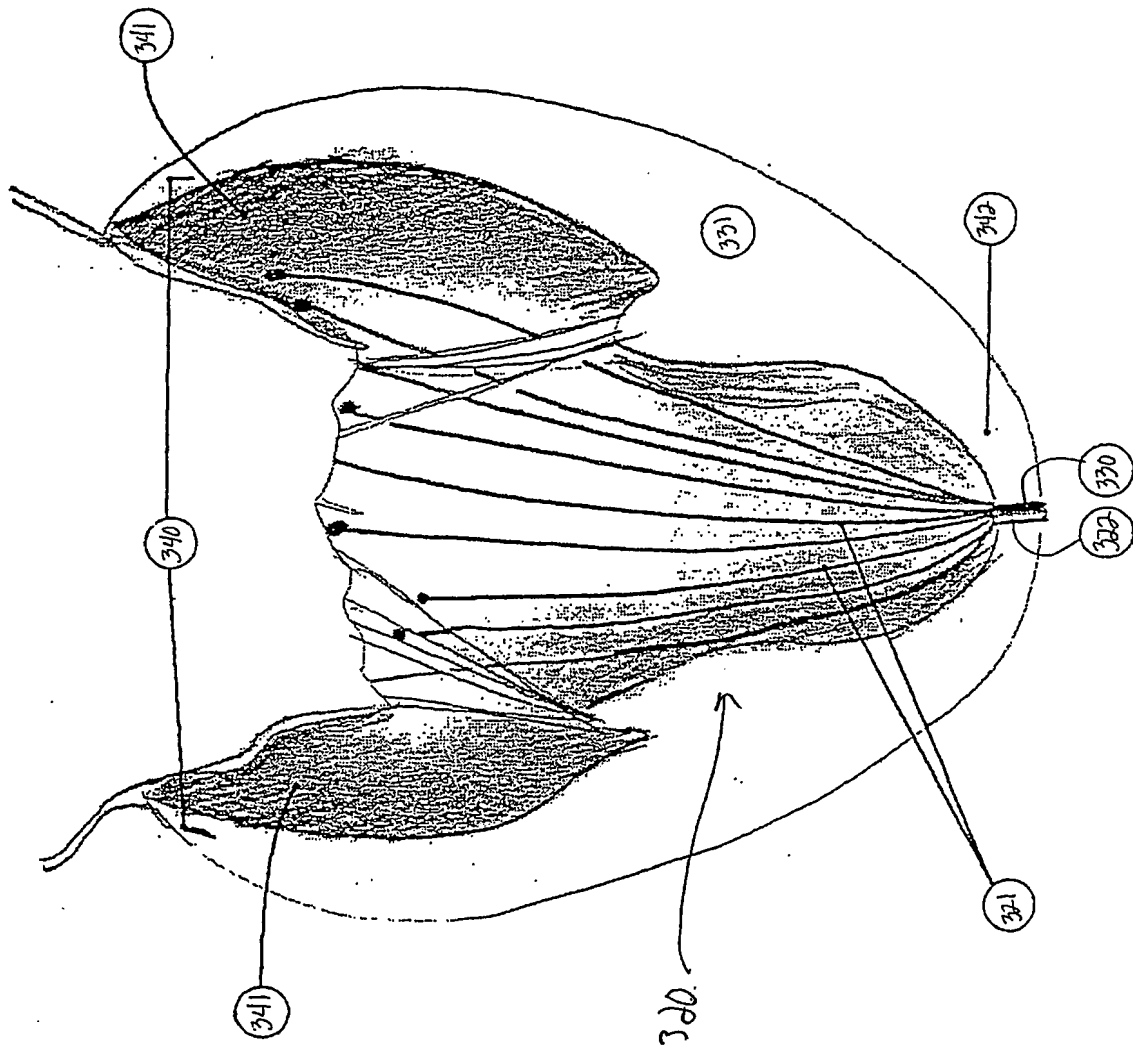


Fig. 34

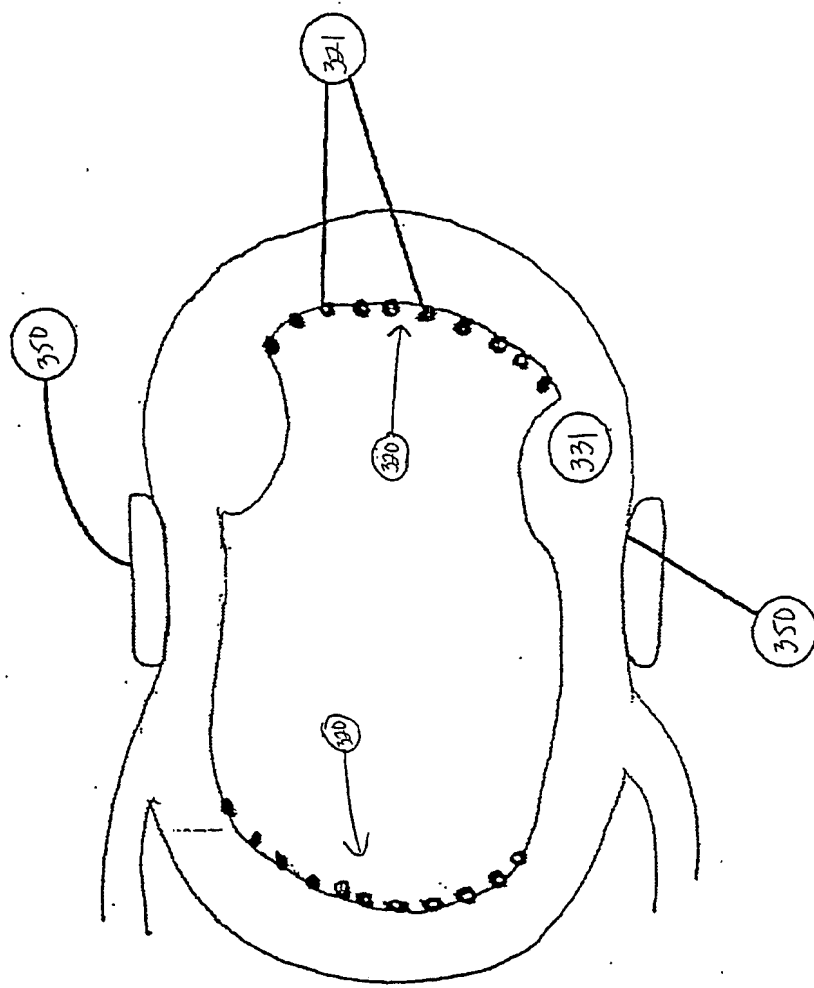
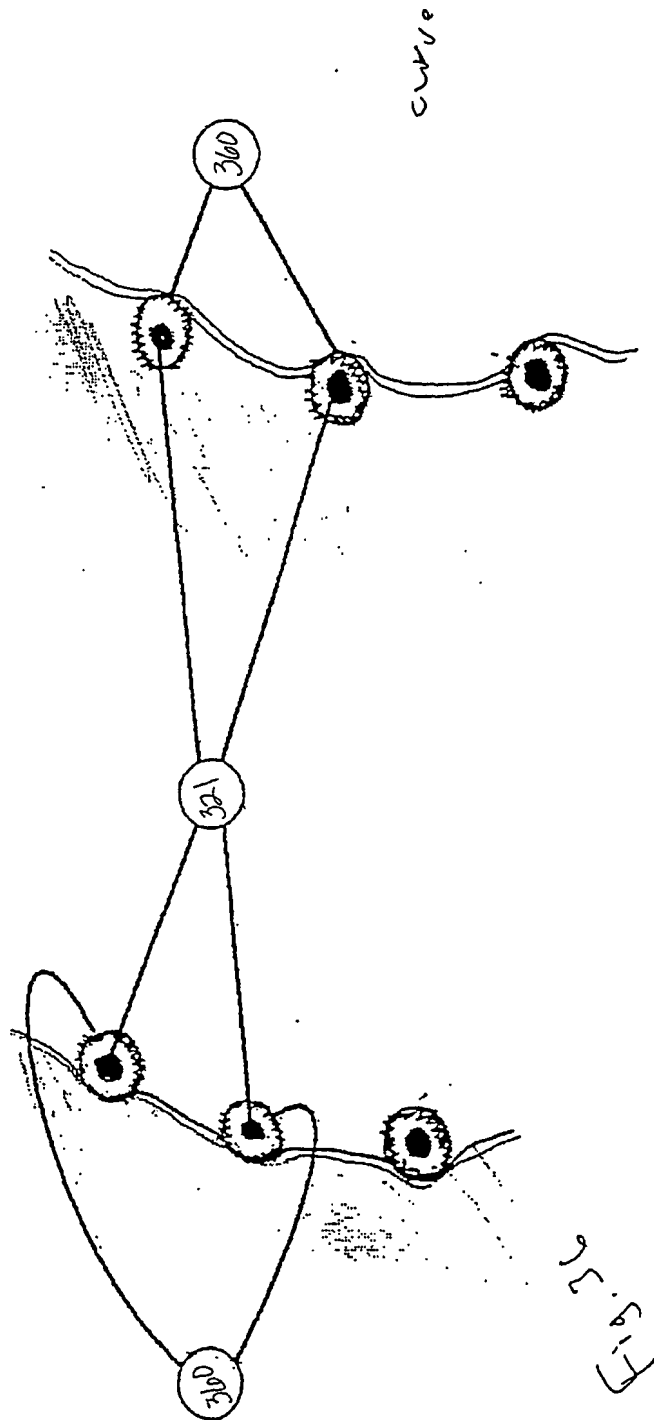


Fig. 35



(cardiac)

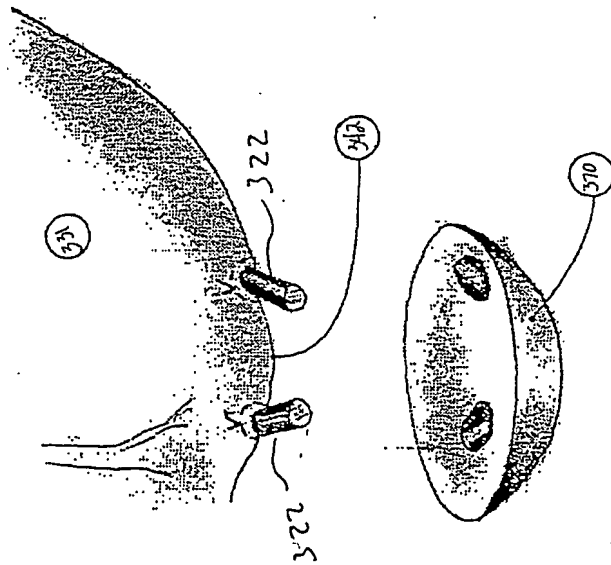


Fig. 17

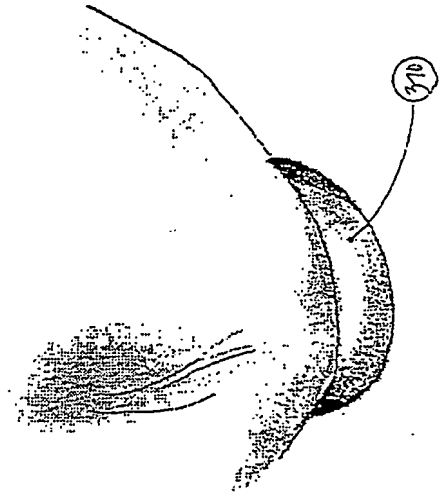


Fig. 18

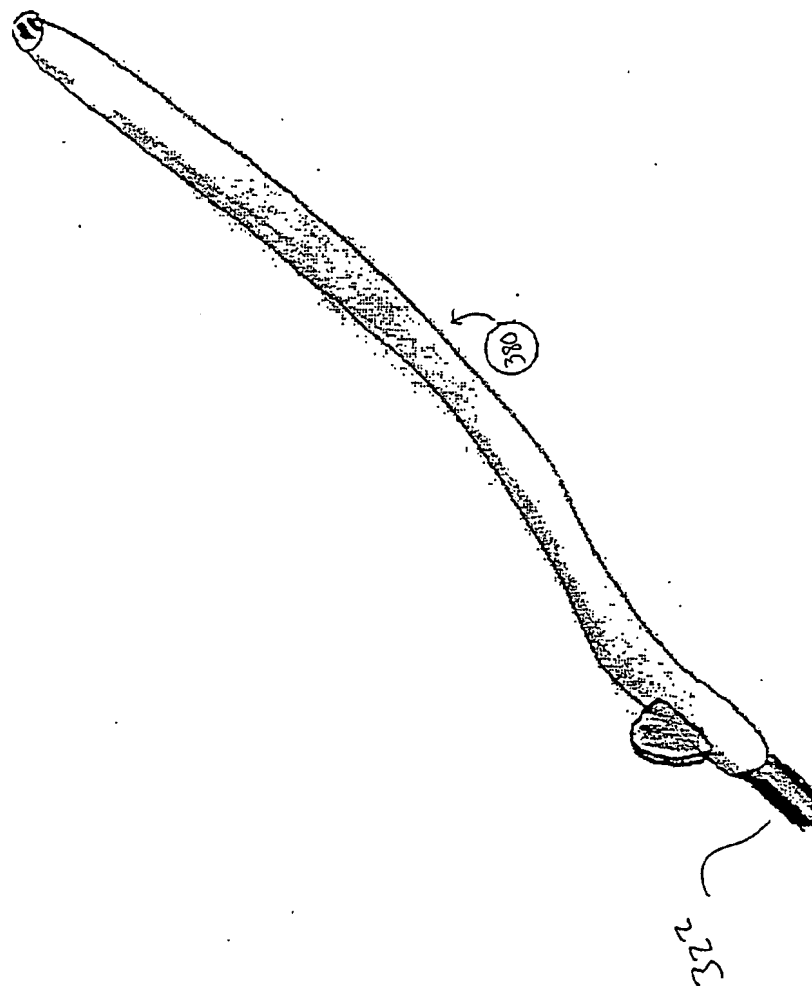
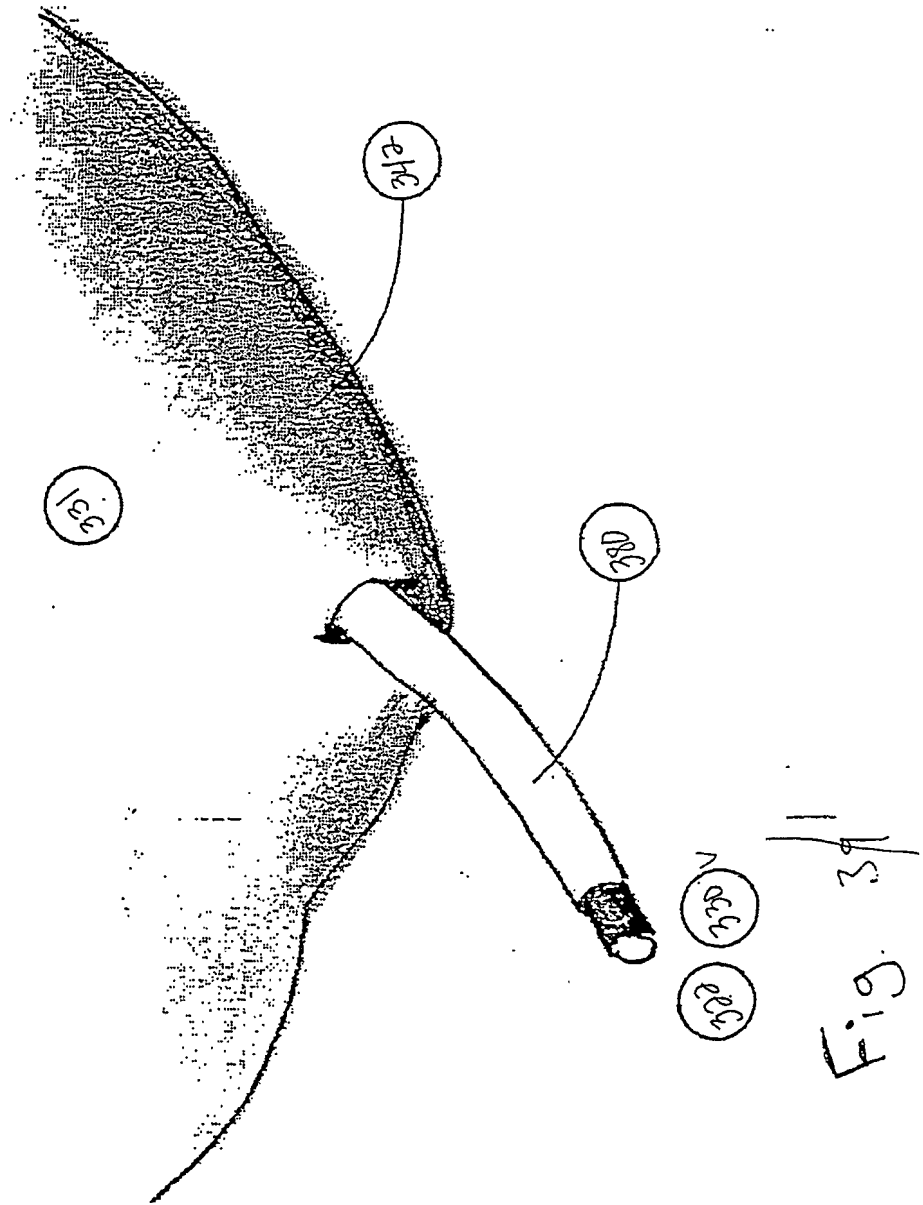
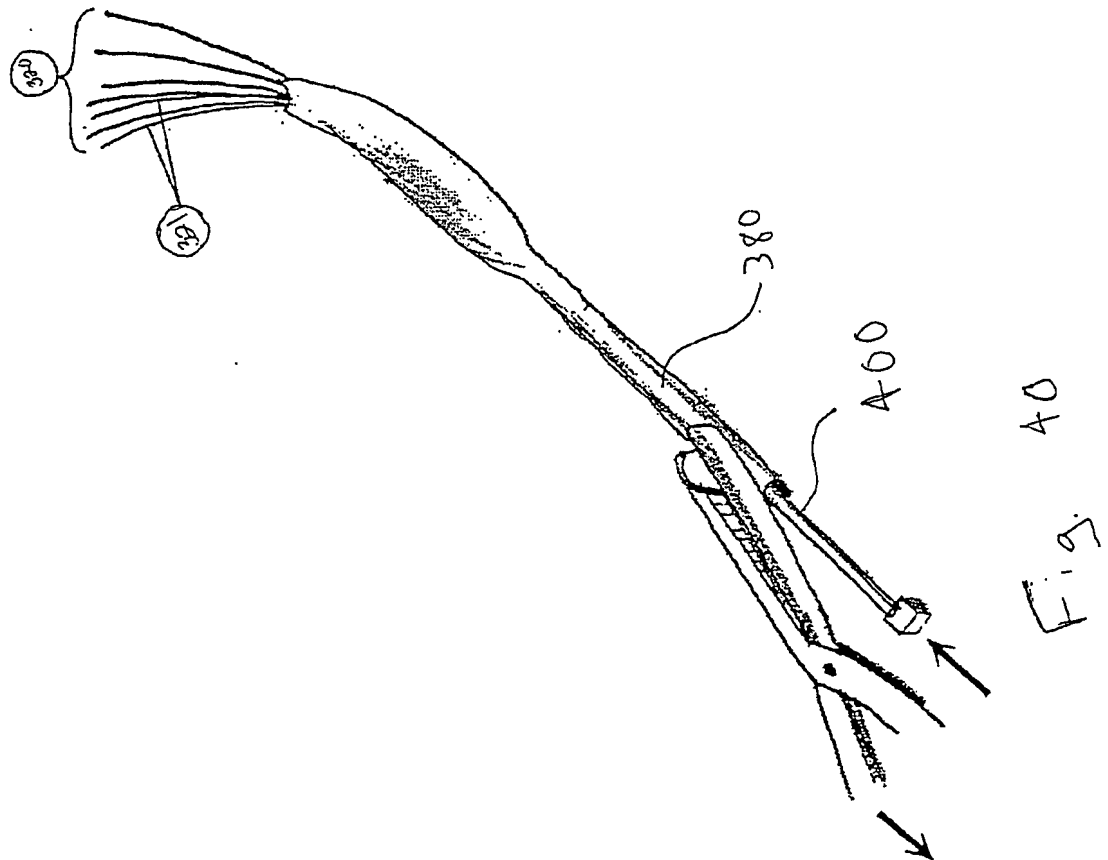
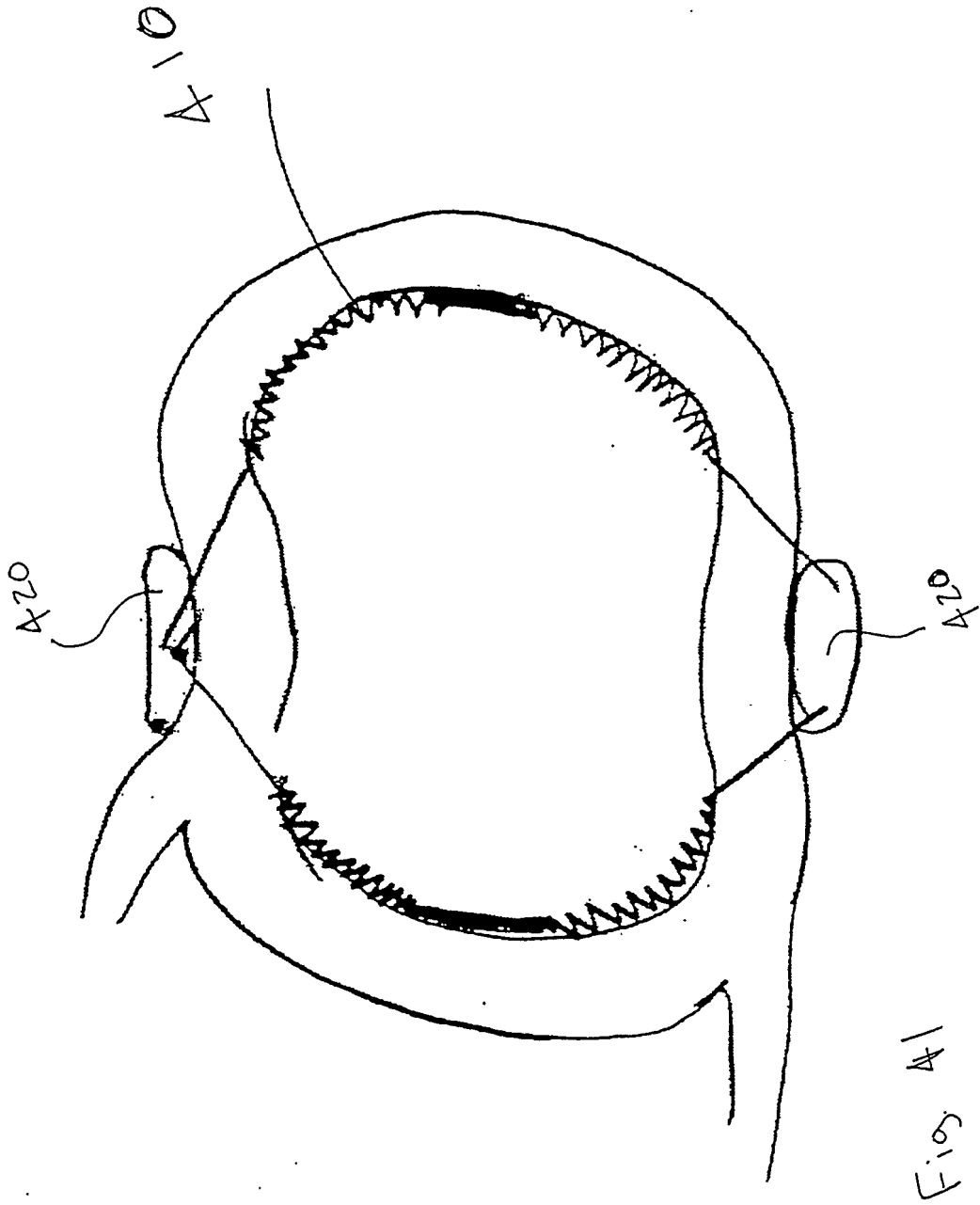


Fig. 38









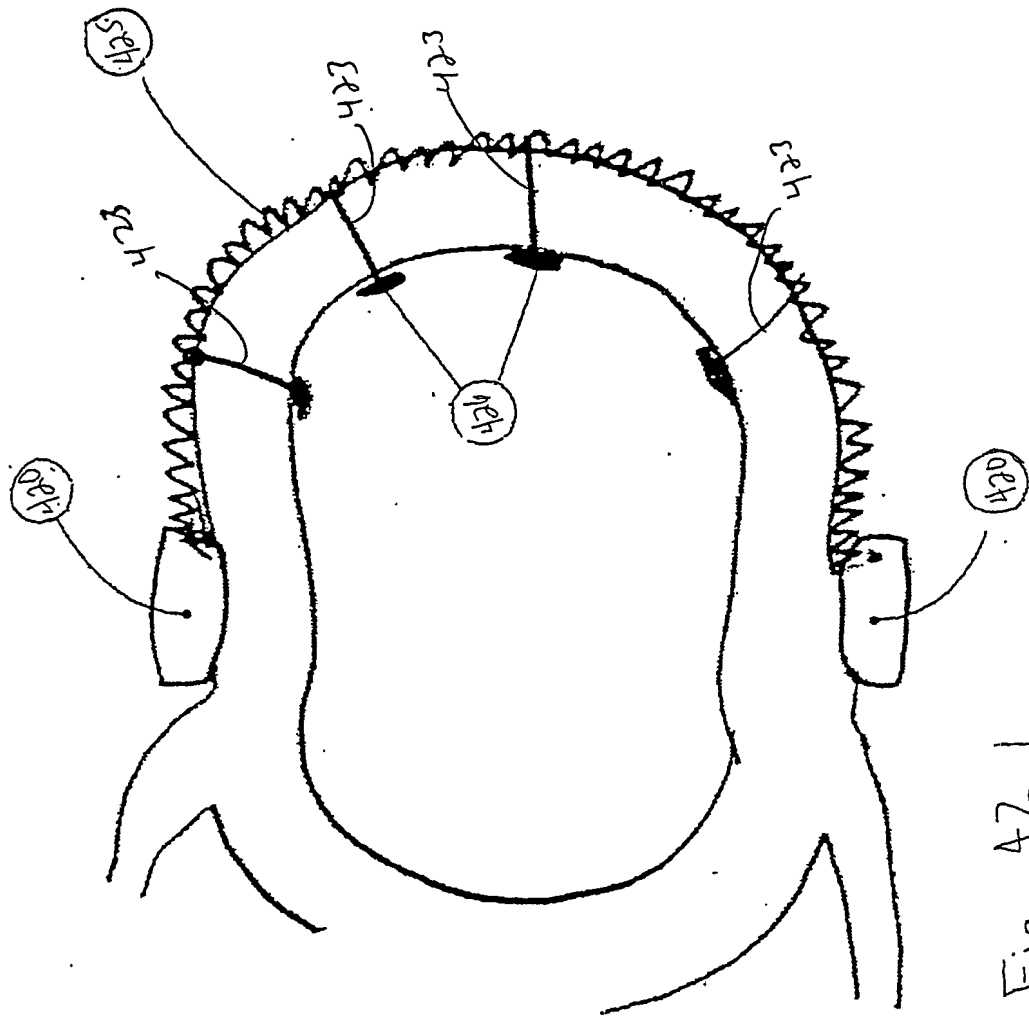


Fig. 421

Fig. 421

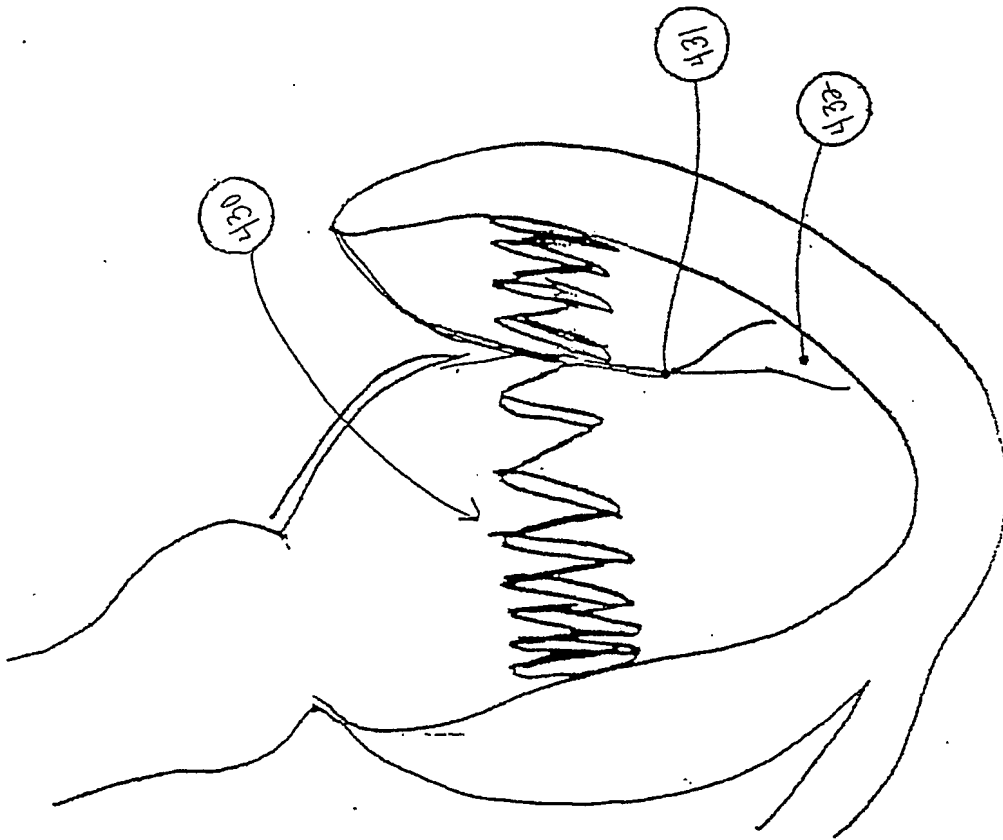


Fig. 43

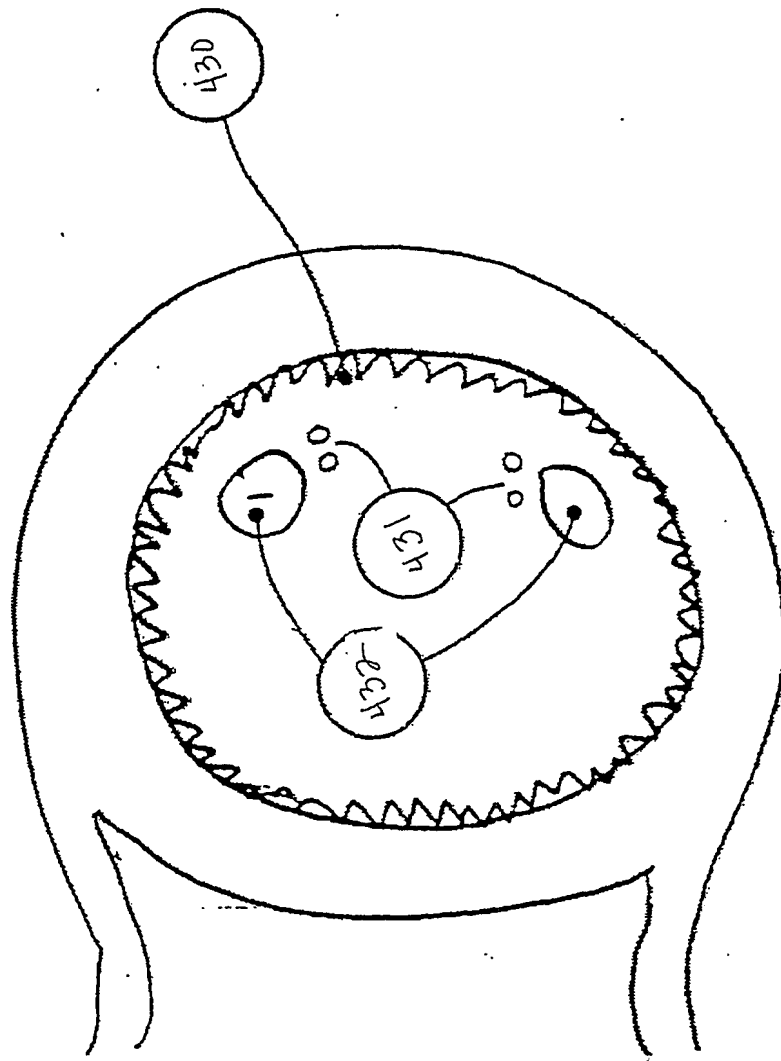


Fig. 44

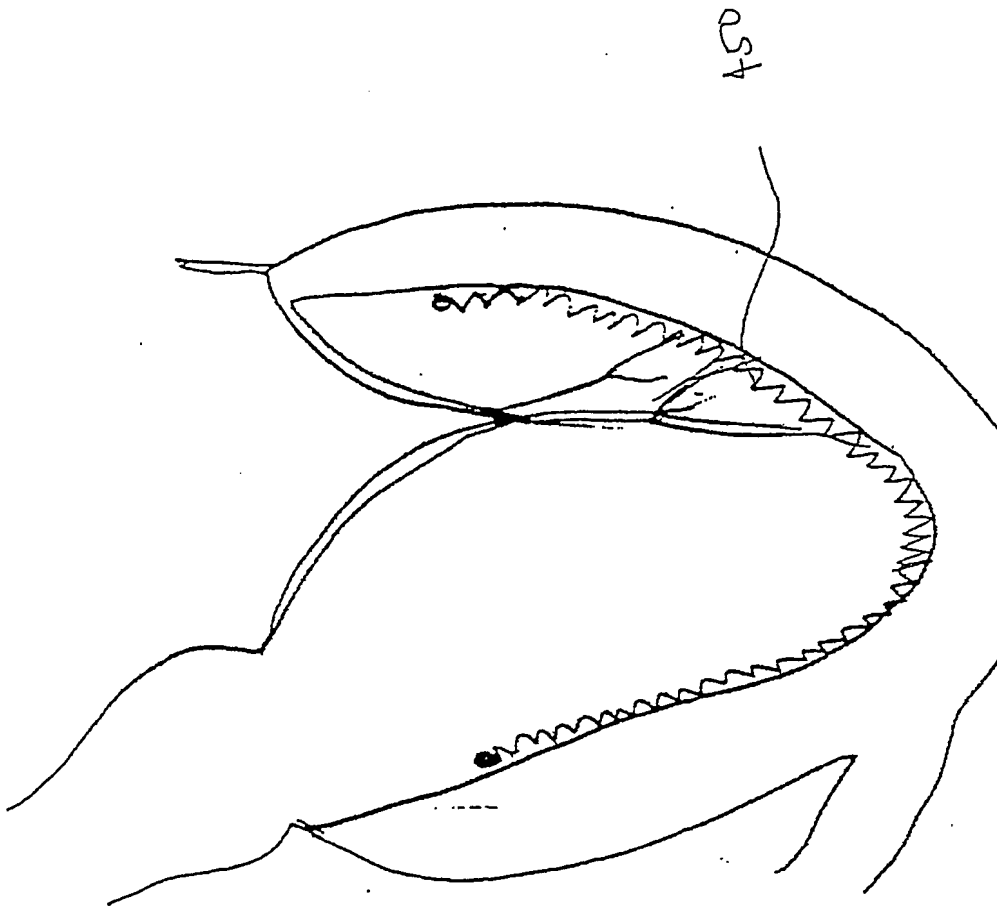


Fig. 45

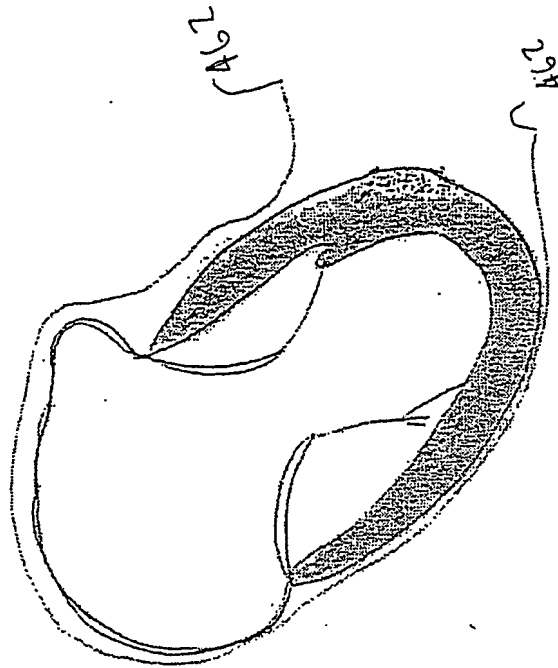


Fig. 46B

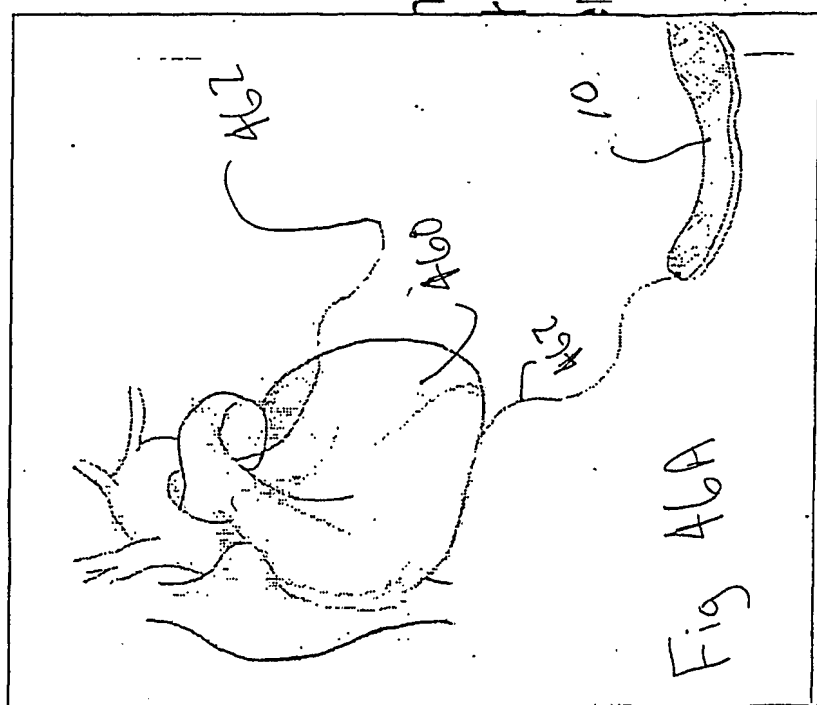


Fig 46A

Fig. 47B

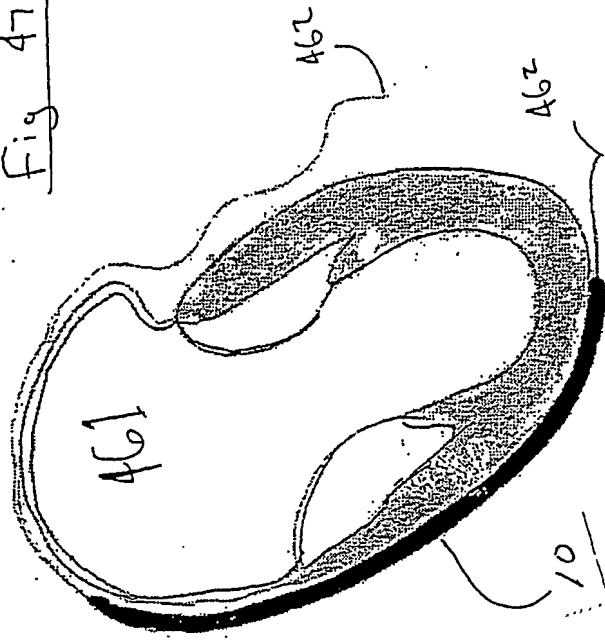
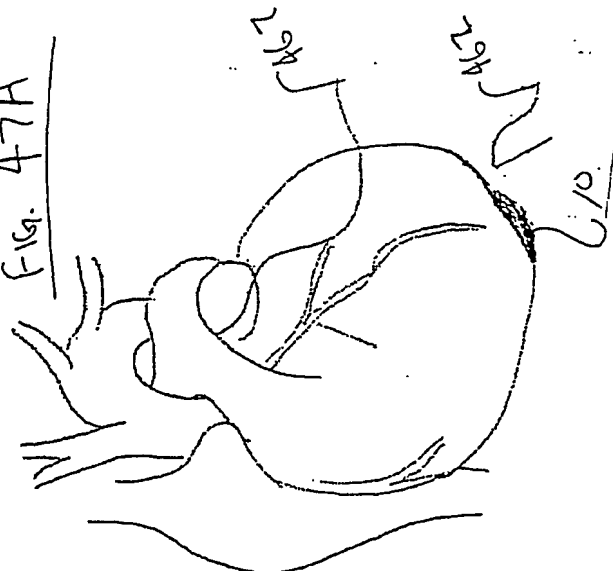


Fig. 47A



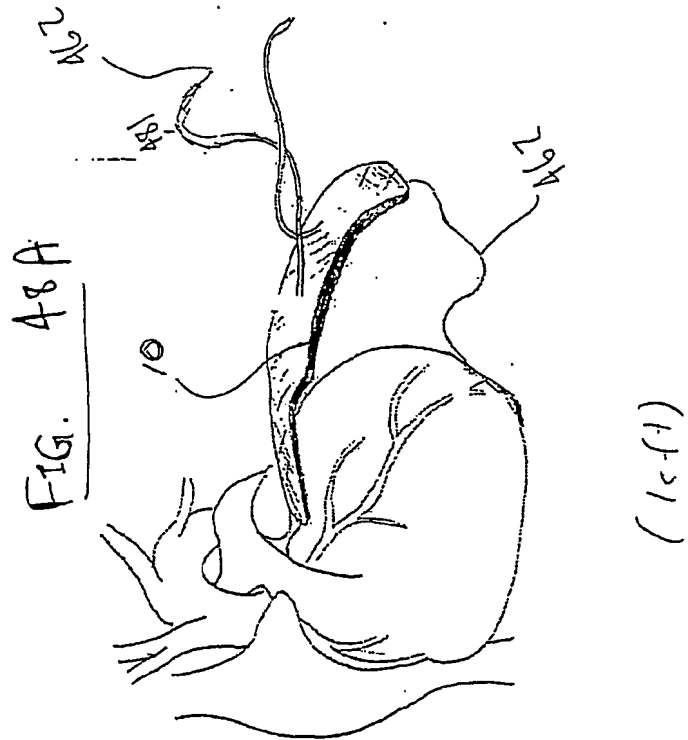
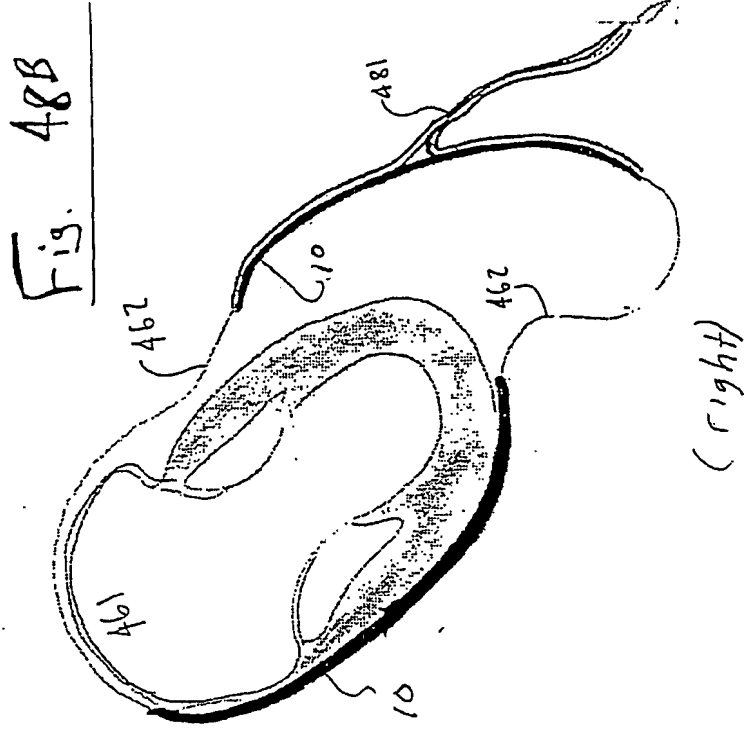


Fig. 49B

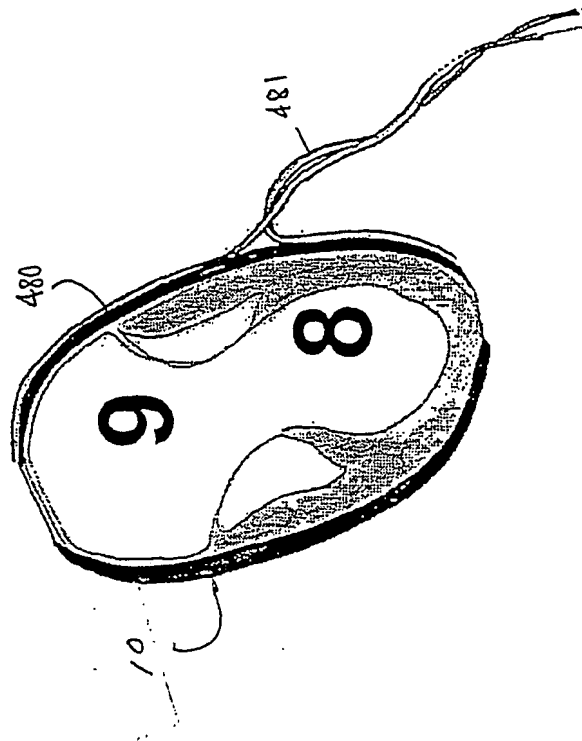


Fig. 49A

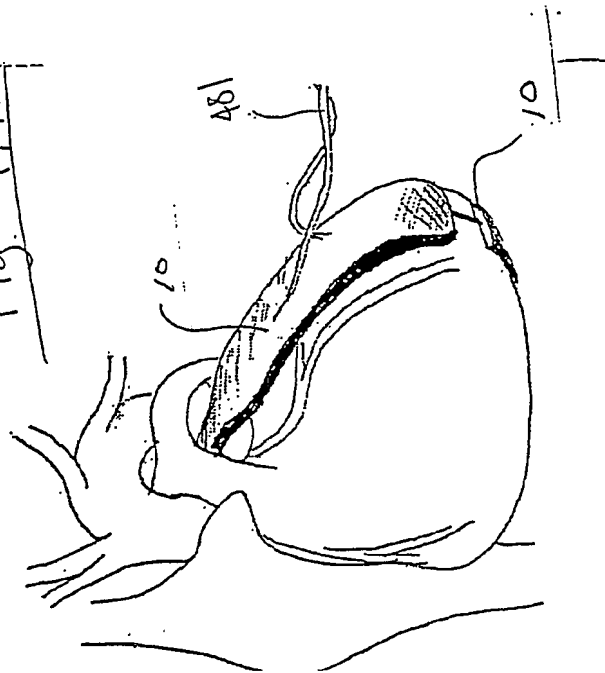




Fig. 50b

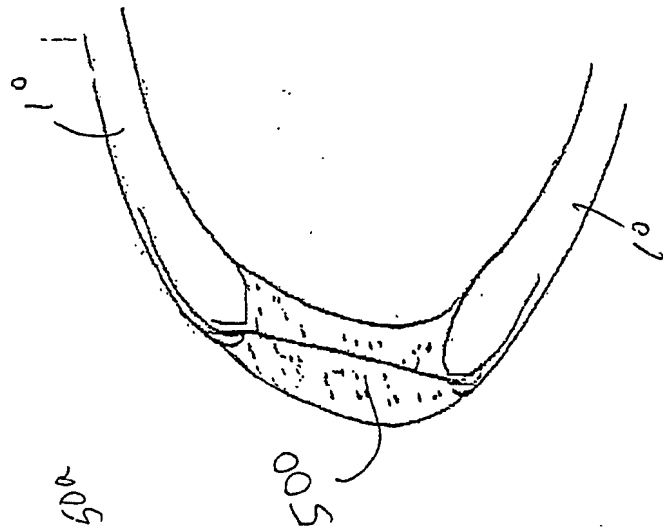
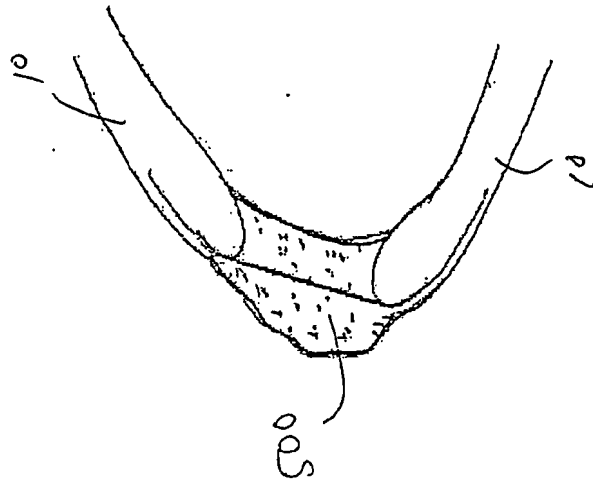
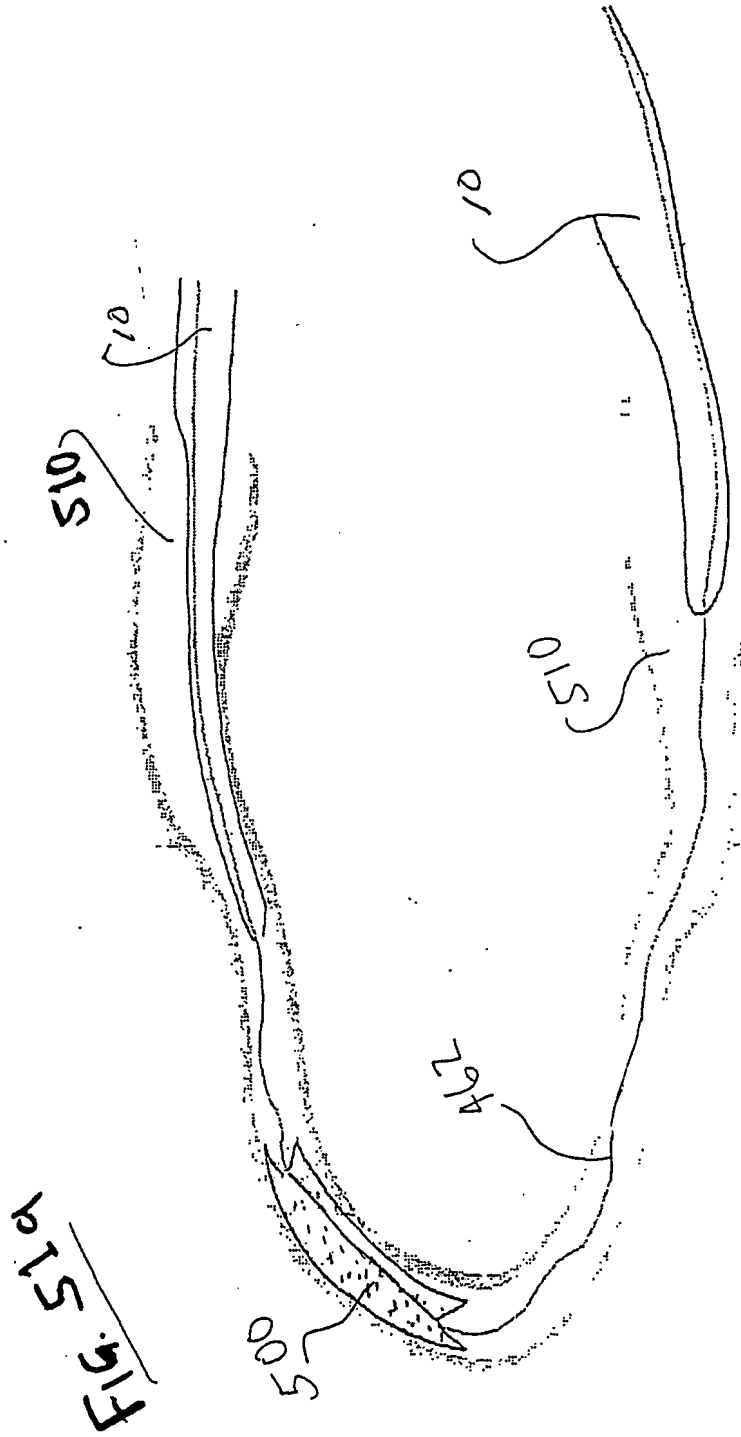
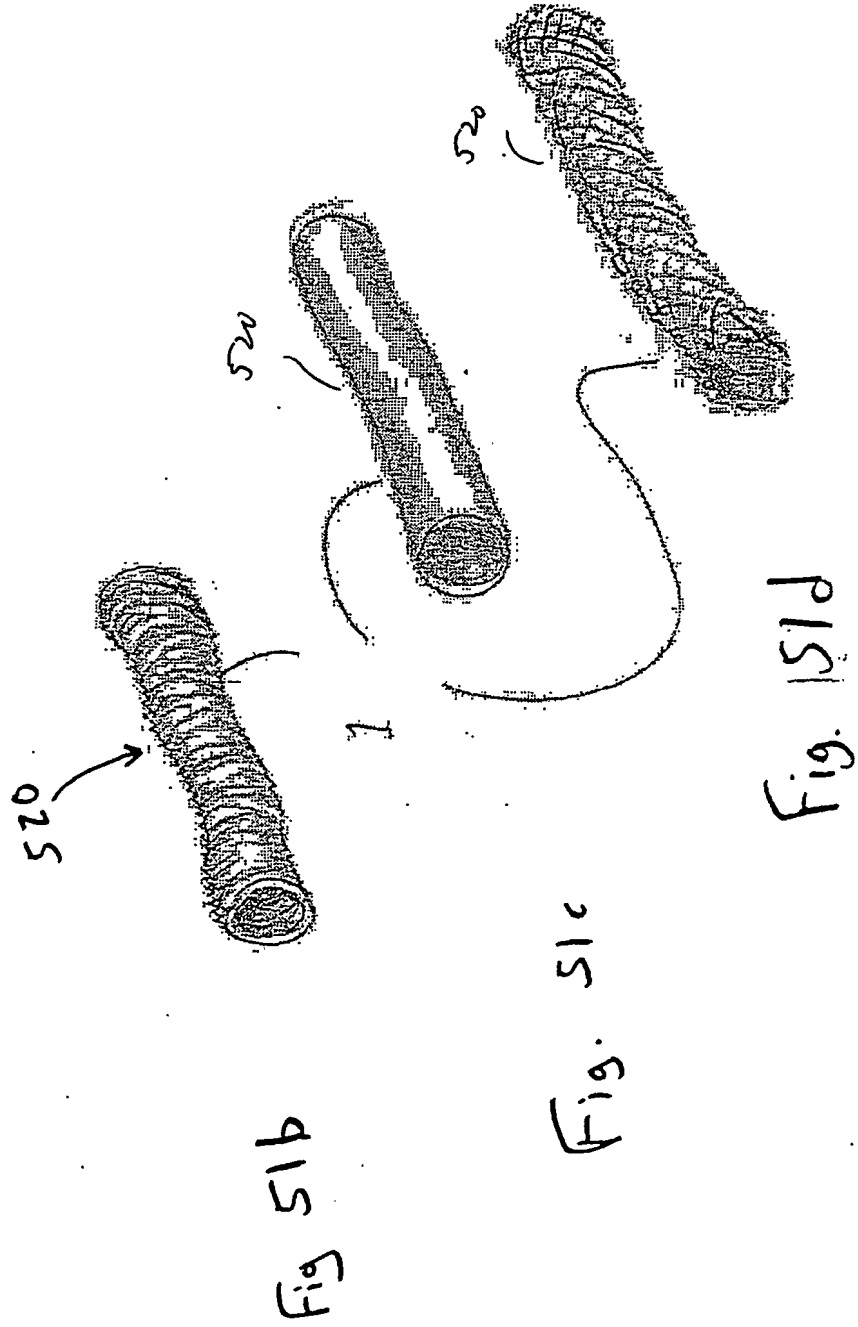
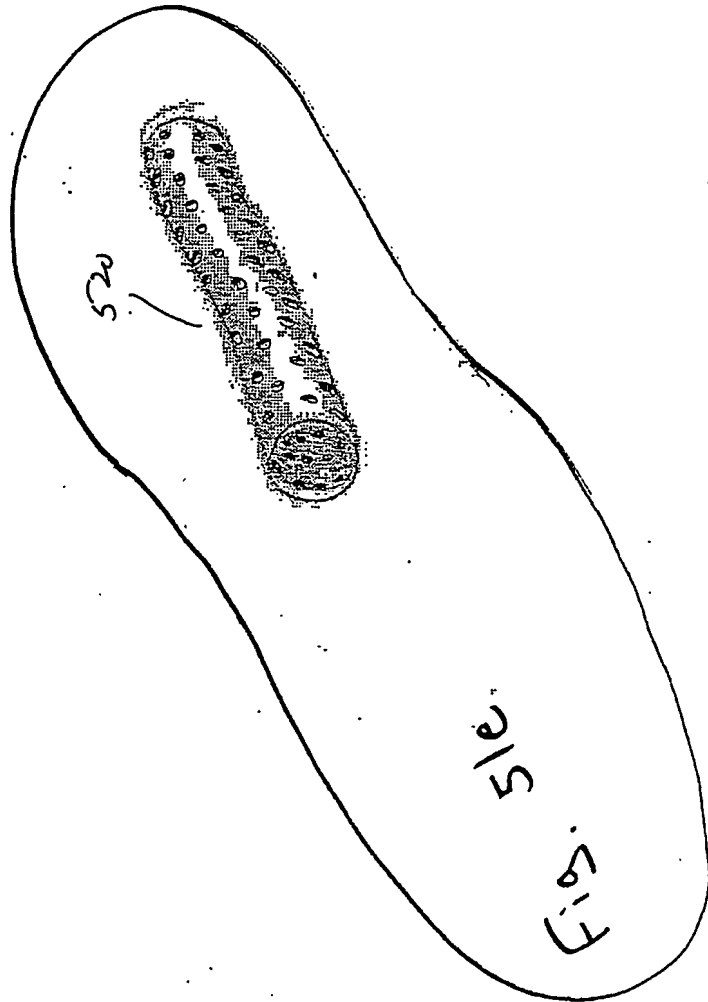


Fig. 50a







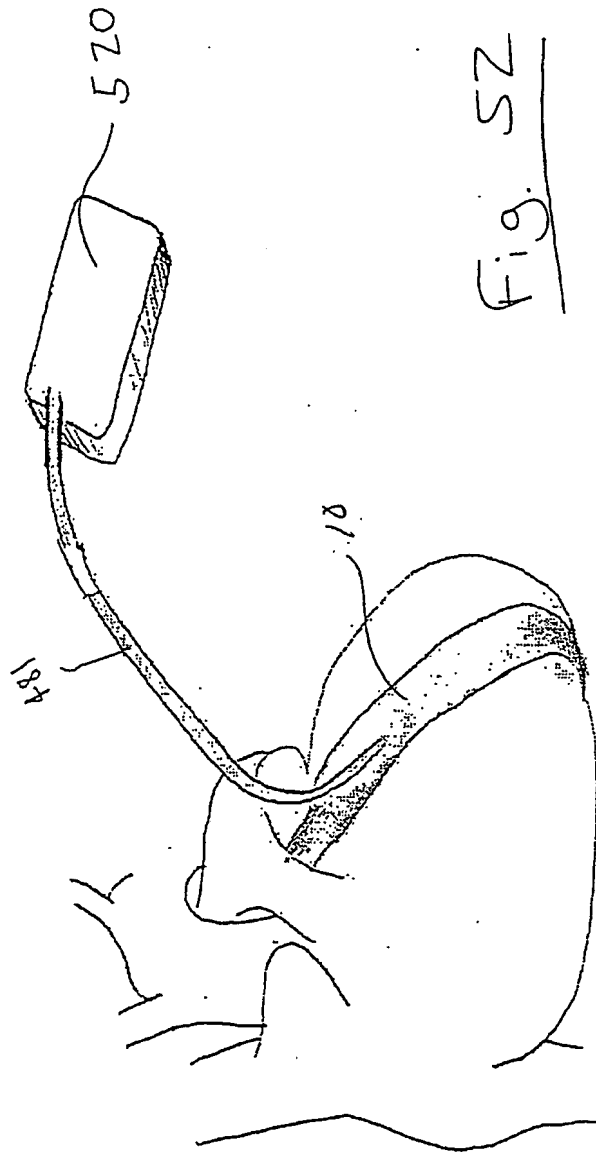


Fig. 52

Fig. 53

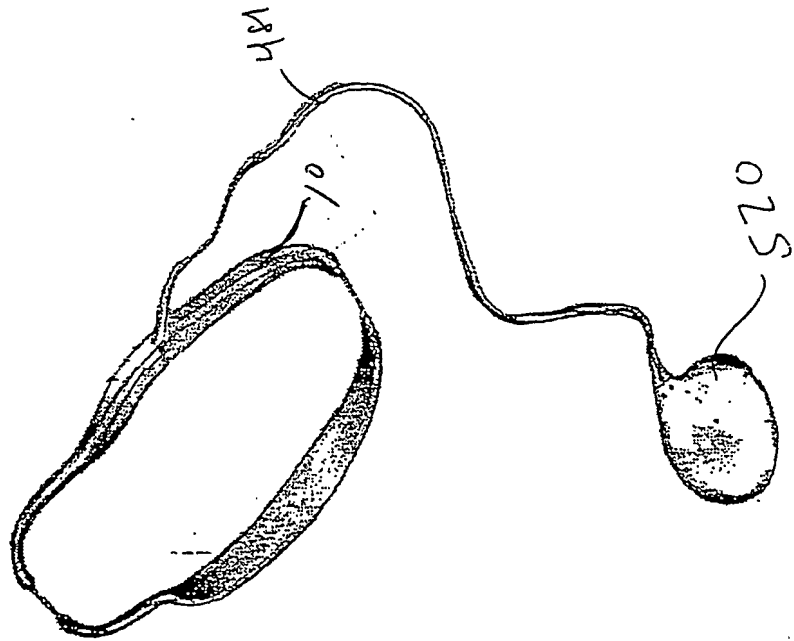


FIG. 54A

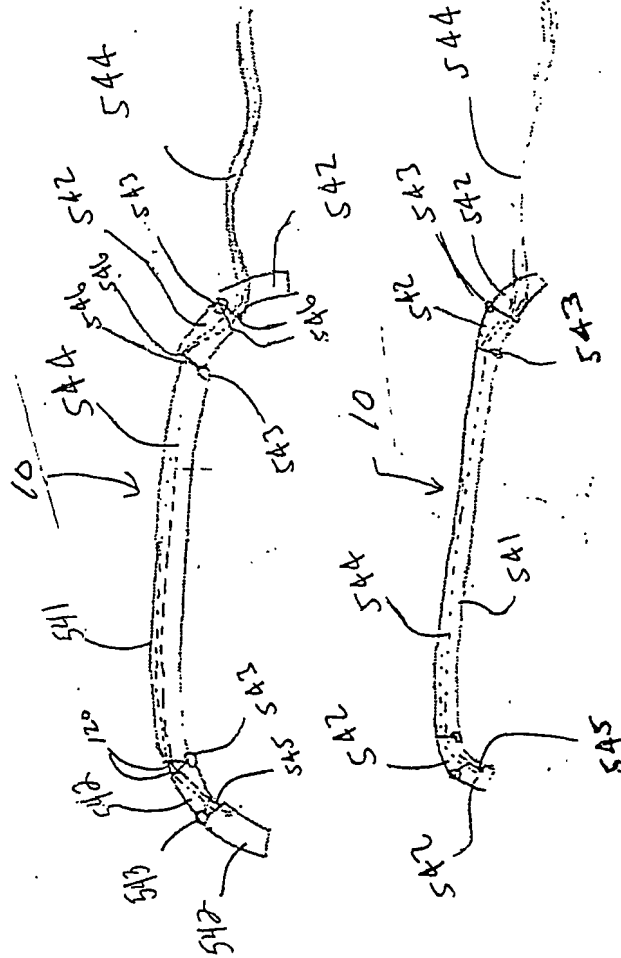
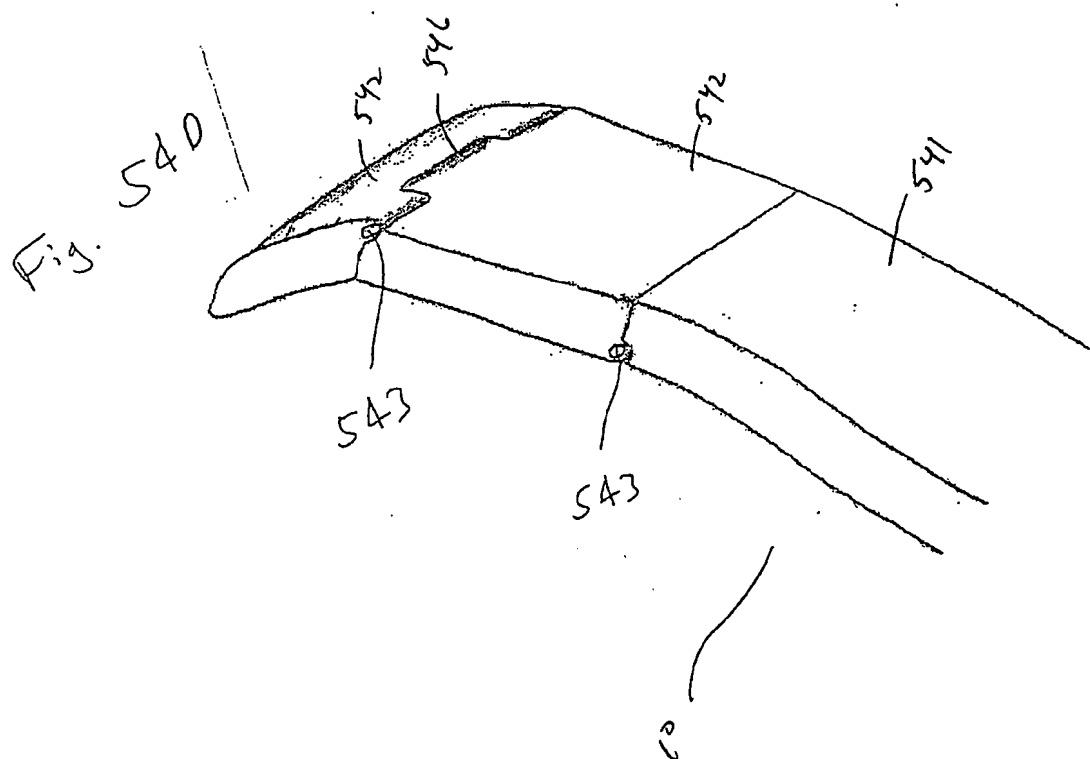
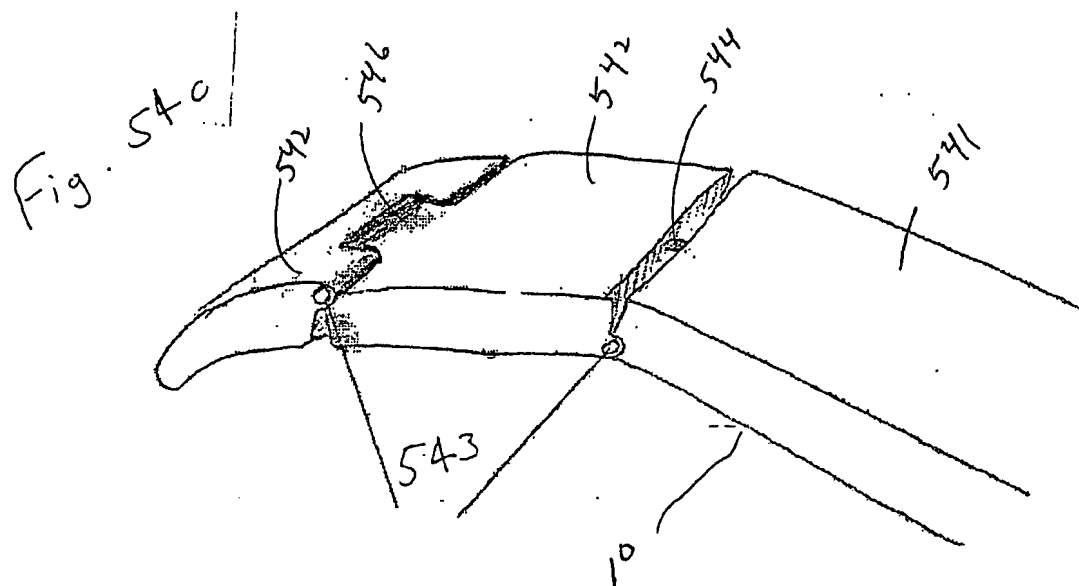


FIG. 54B







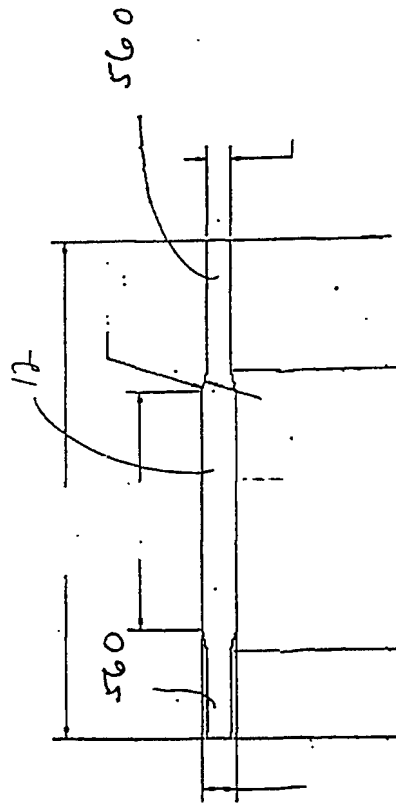
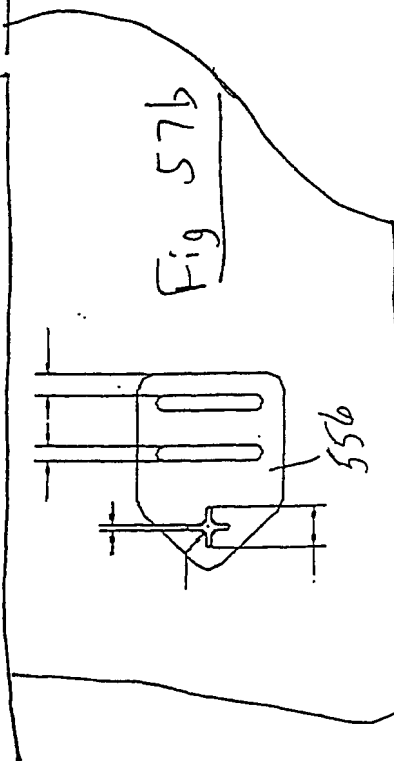
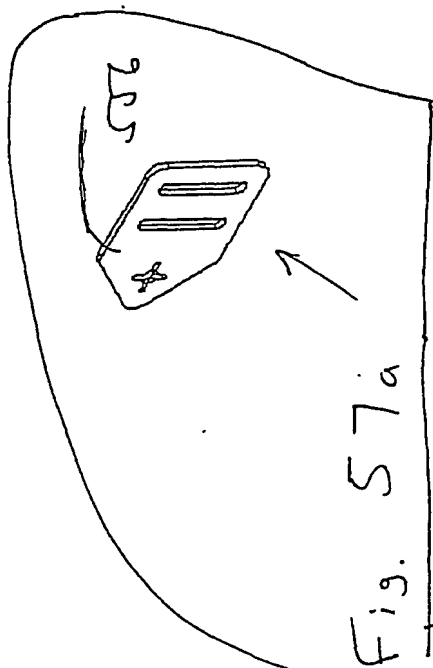


Fig. 56

Fig. 52

CONFIDENTIAL



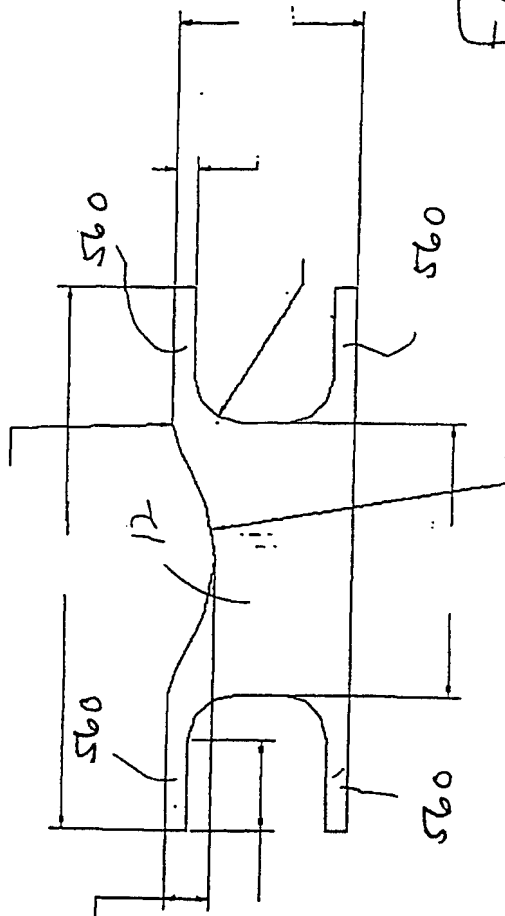
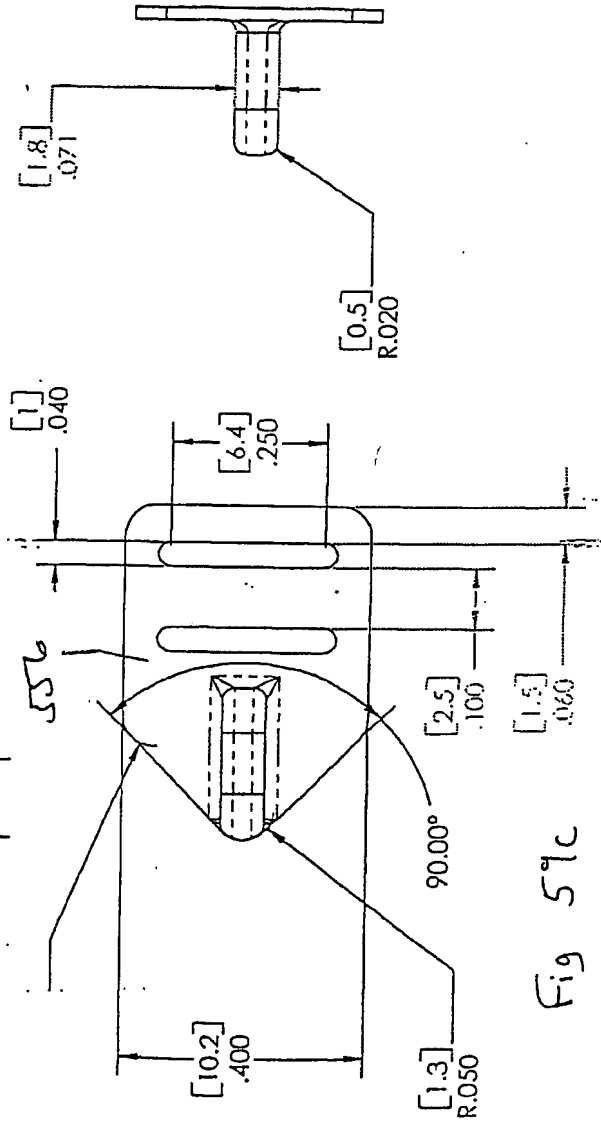
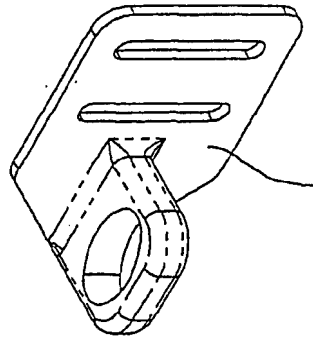
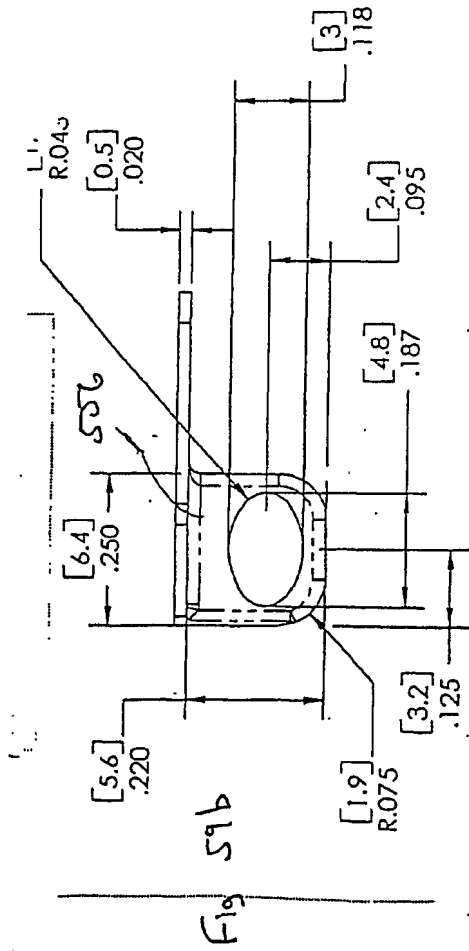


Fig. 58



Notes:

1. Material: LDPE
2. Quantity: 2

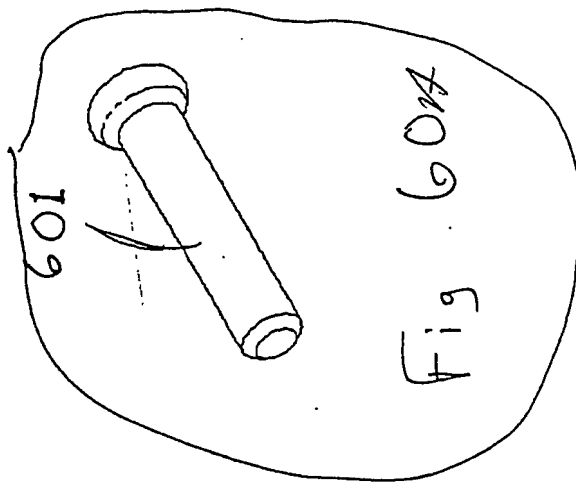


Fig. 60B

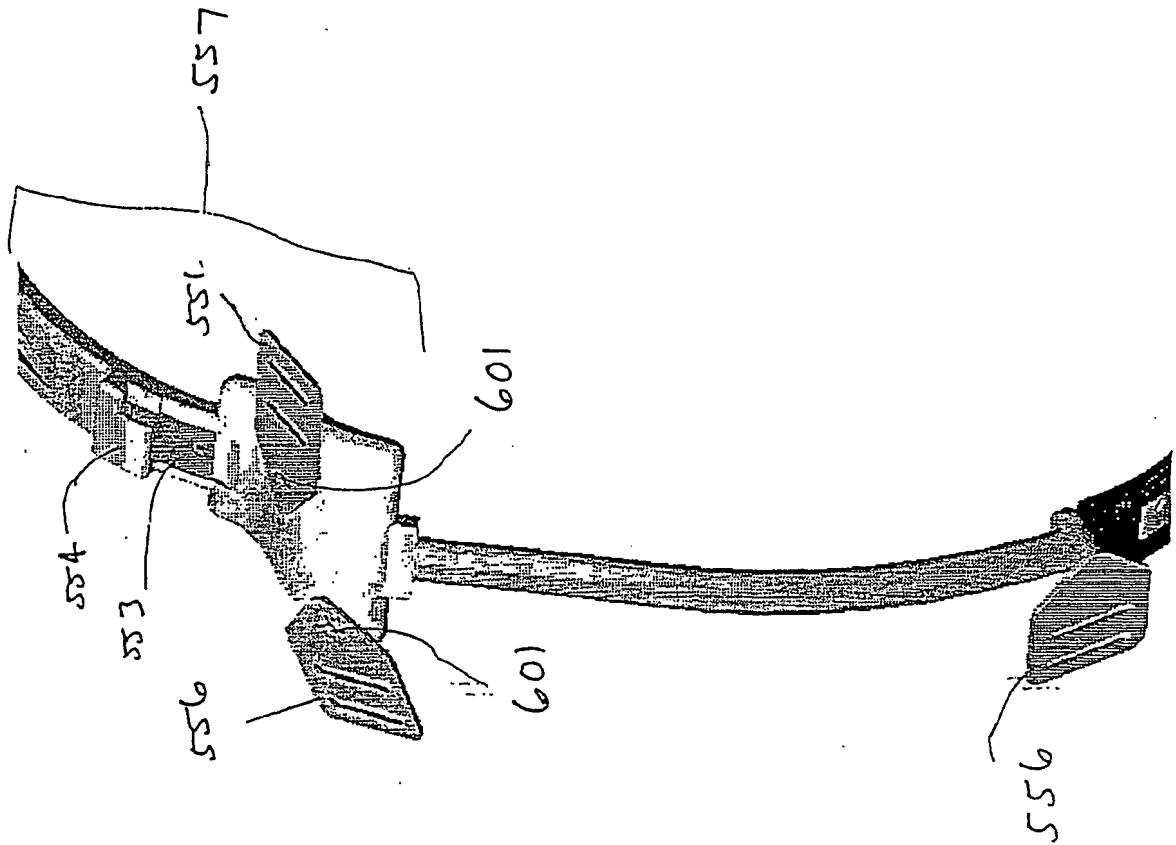


Fig. 61

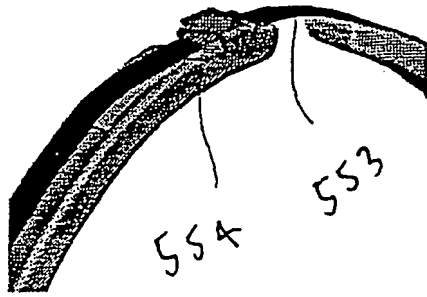


Fig. 62



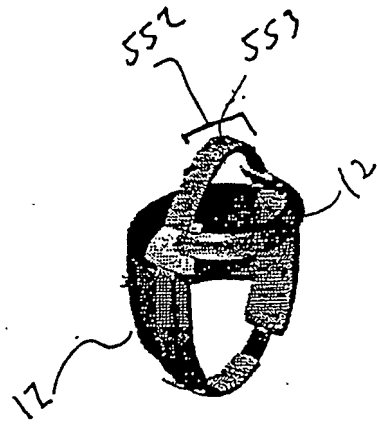


Fig 63a

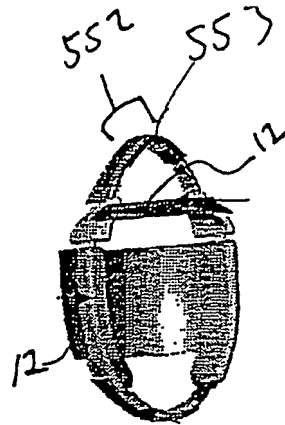


Fig 63b

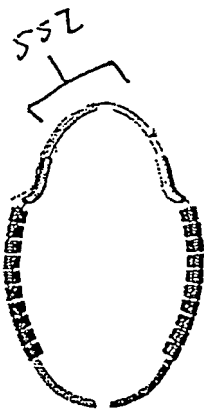


Fig 64a

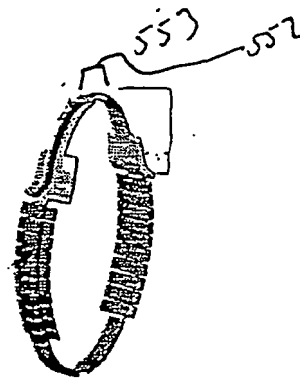


Fig. 64b

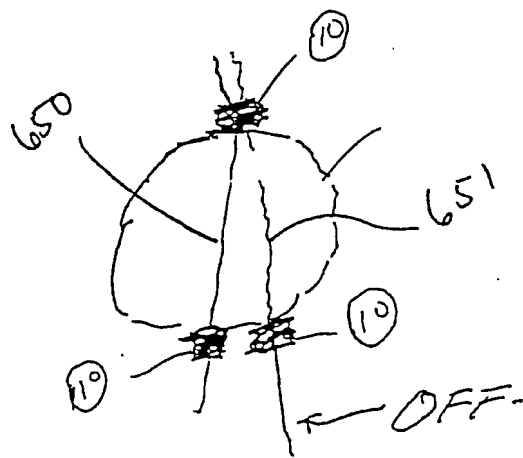


Fig. 65

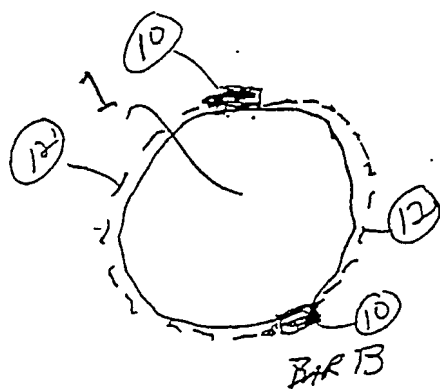


Fig. 66

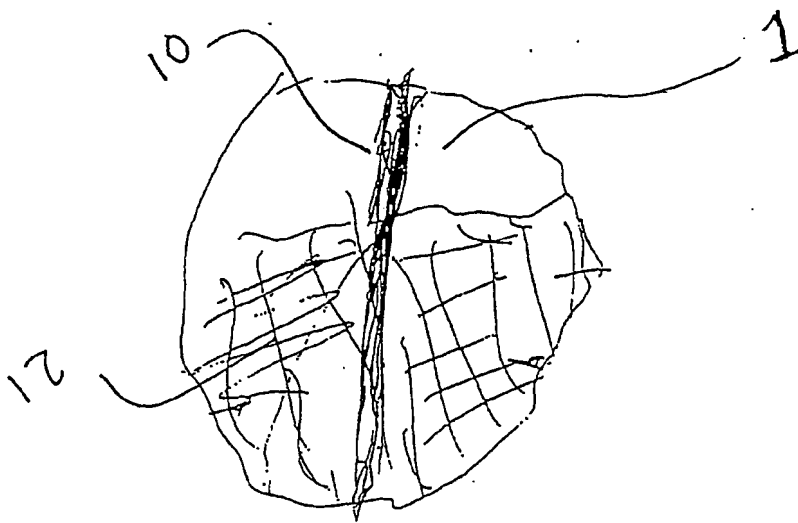


Fig. 67

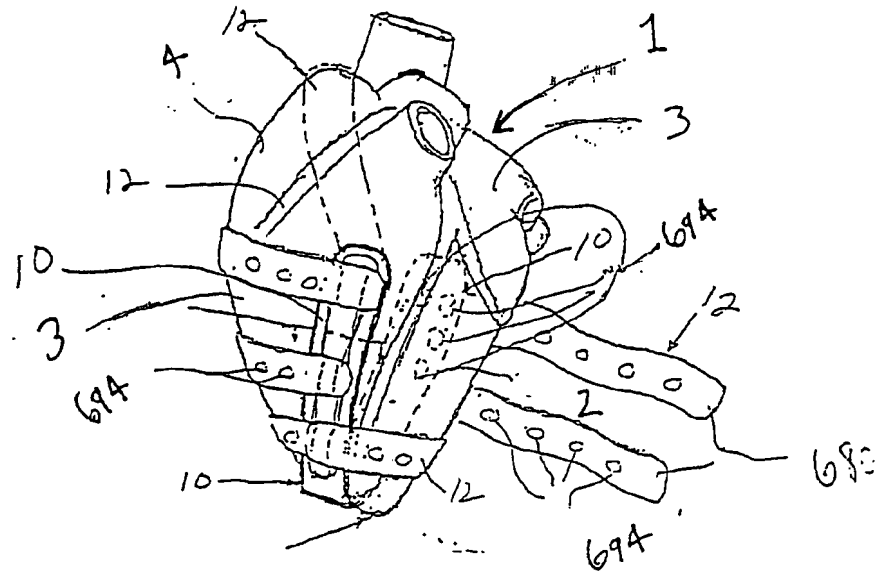


Fig. 68

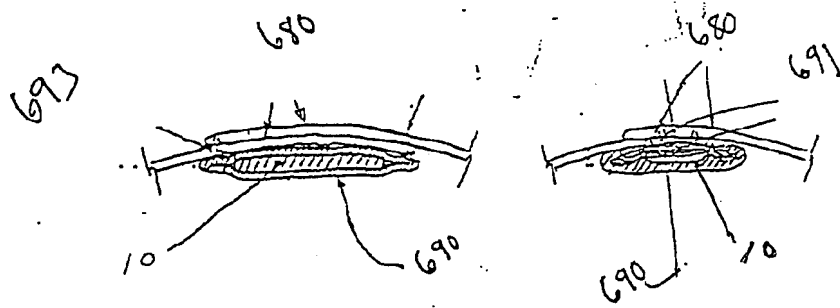
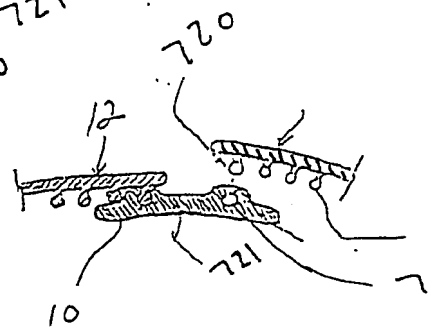
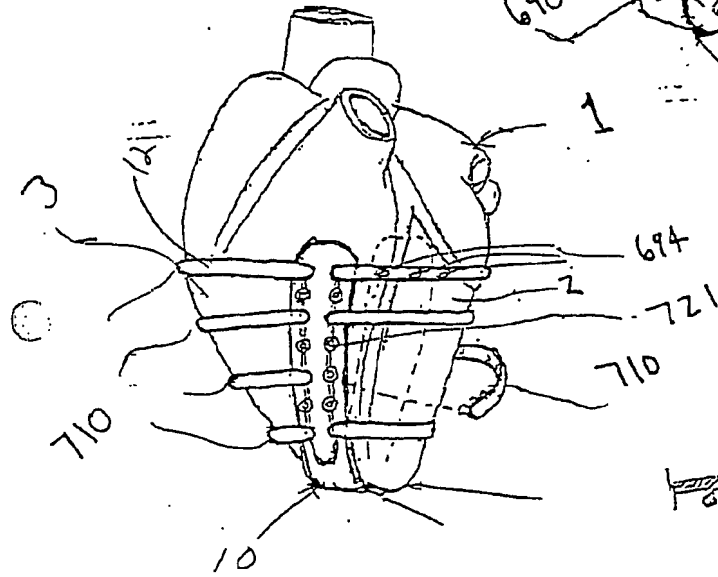
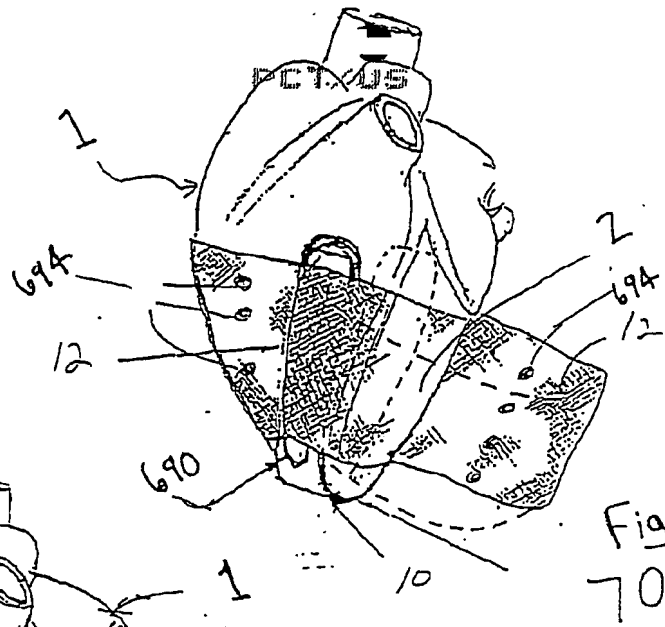


Fig. 69a

Fig. 69b



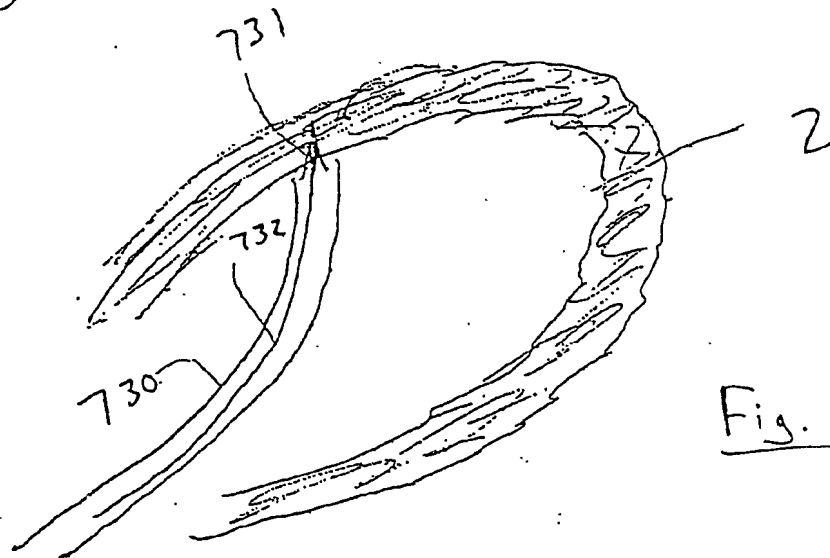
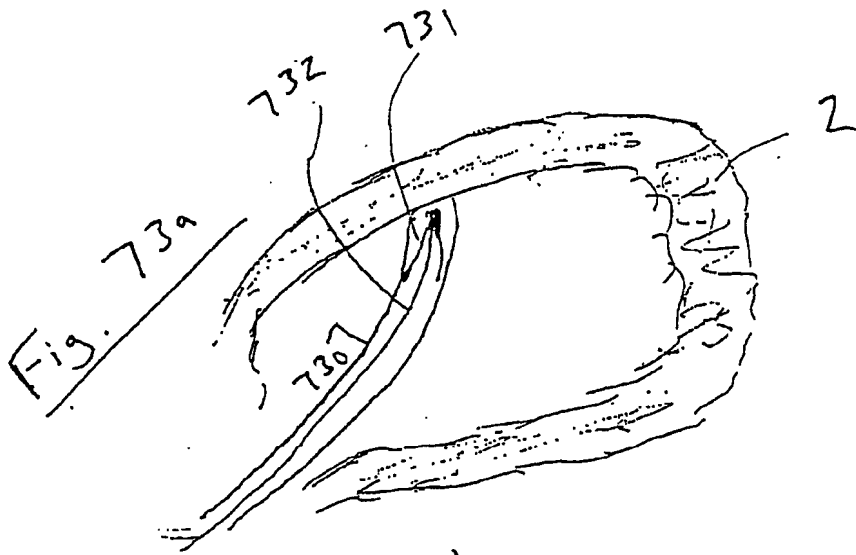


Fig. 73b

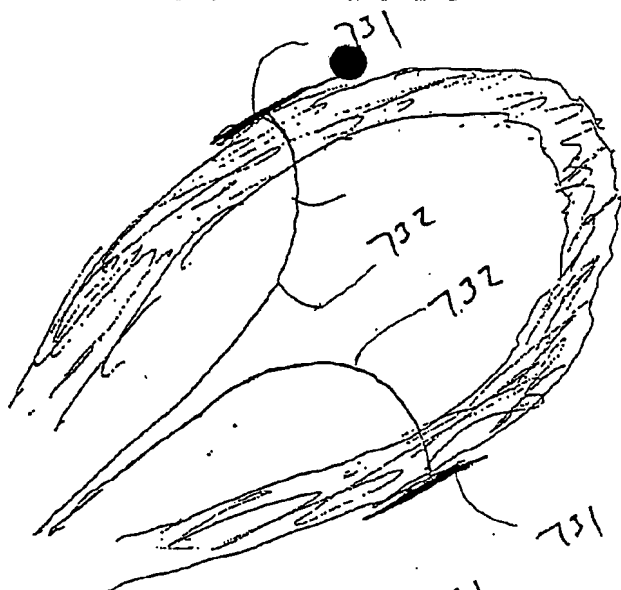


Fig. 74a

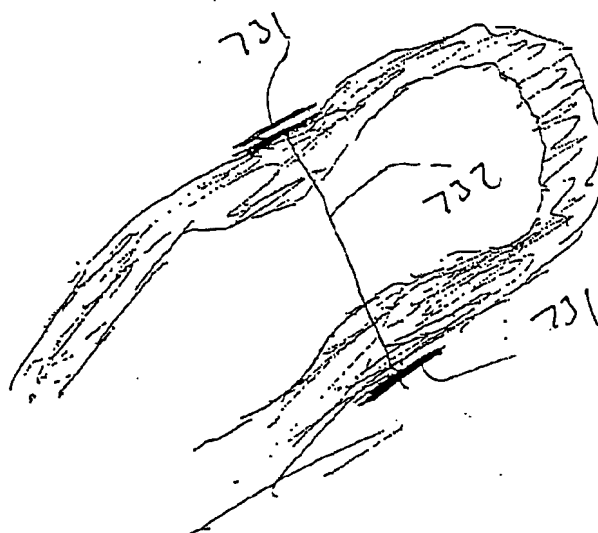


Fig. 74b



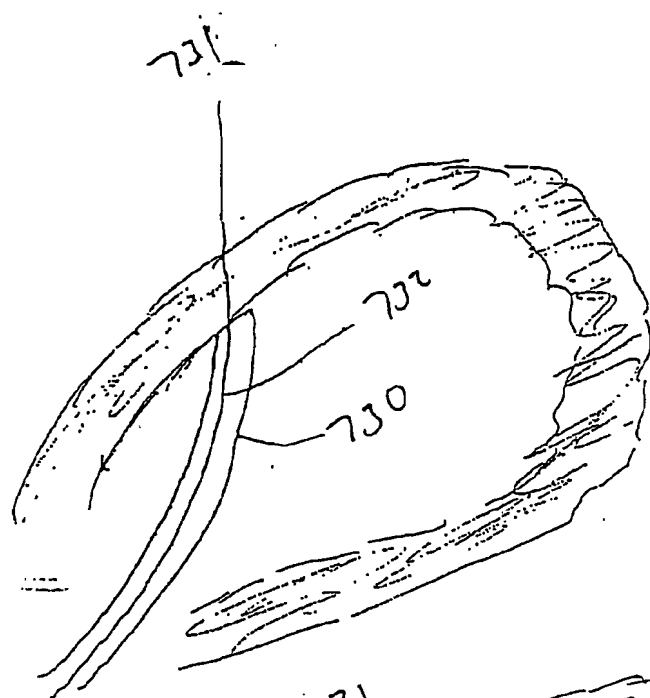


Fig. 75a

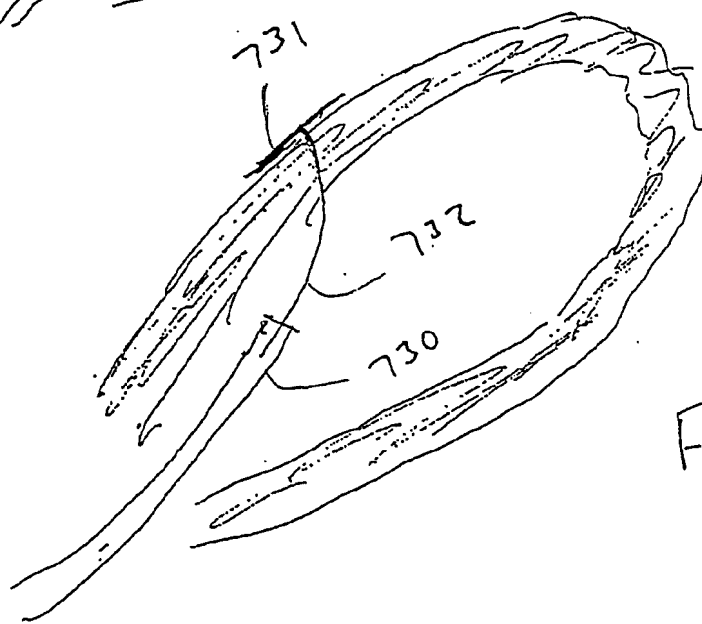


Fig. 75b

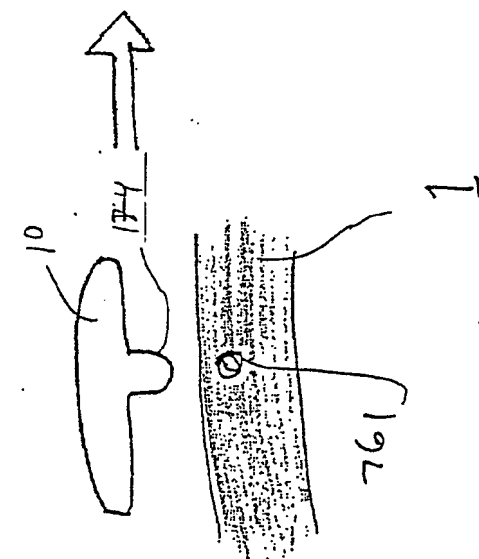


Fig. 76a

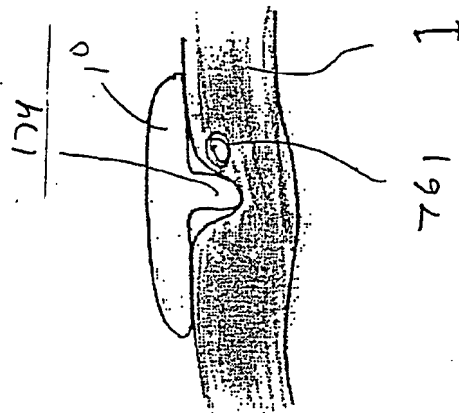


Fig. 76b

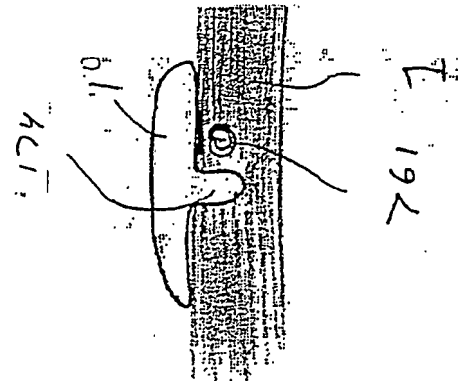


Fig. 76c

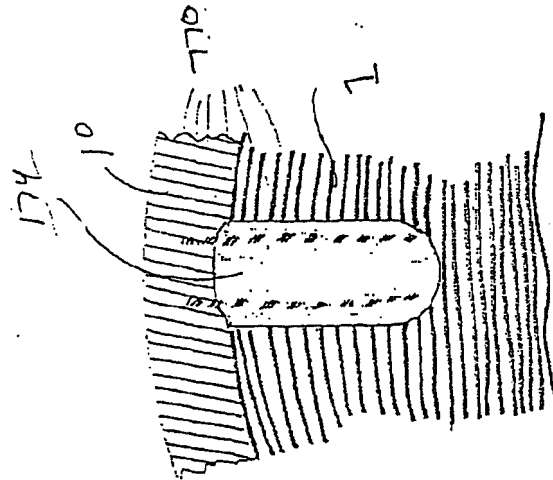


Fig. 77a

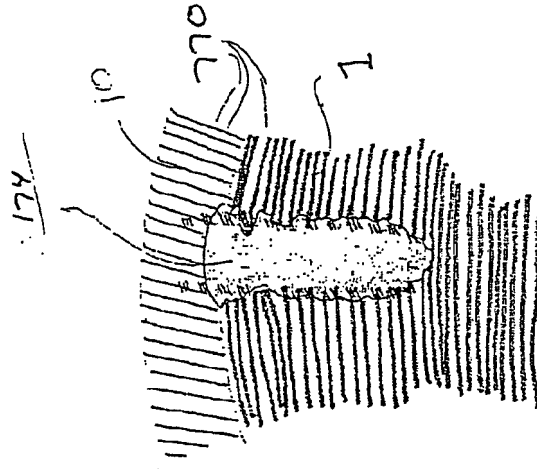


Fig. 77b

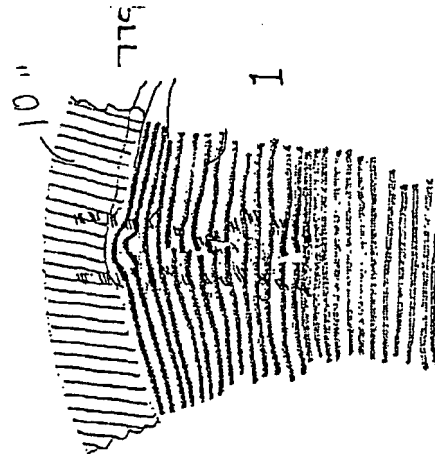
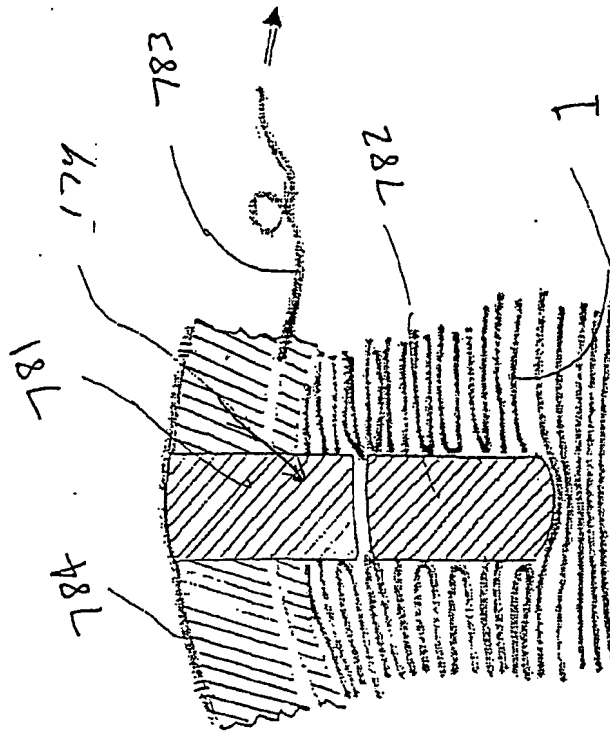
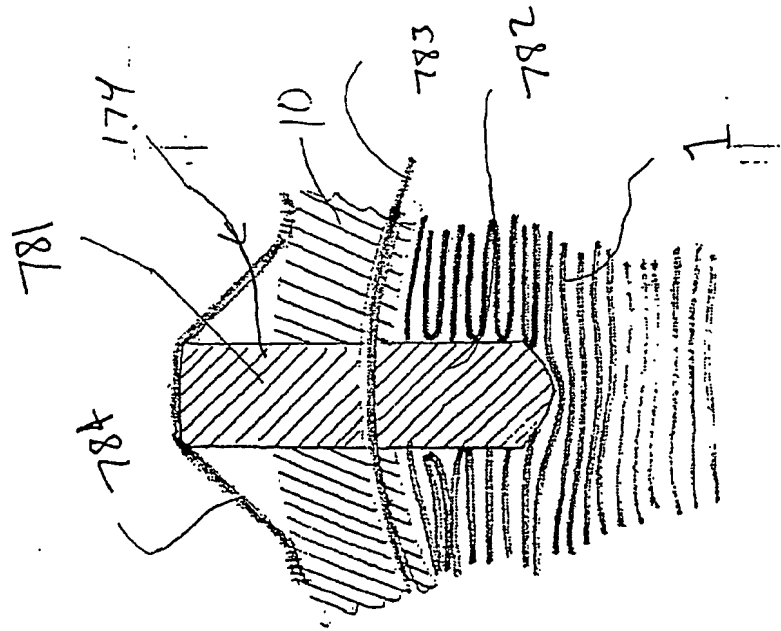


Fig. 77c



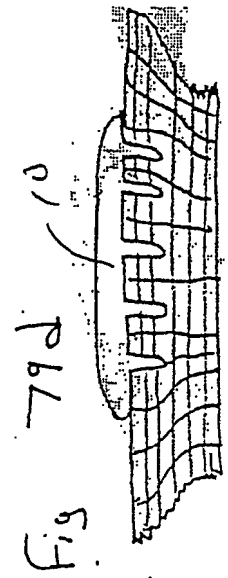
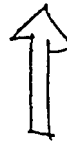
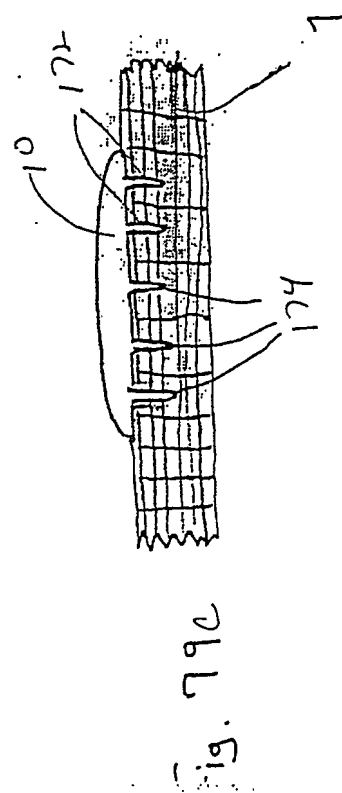
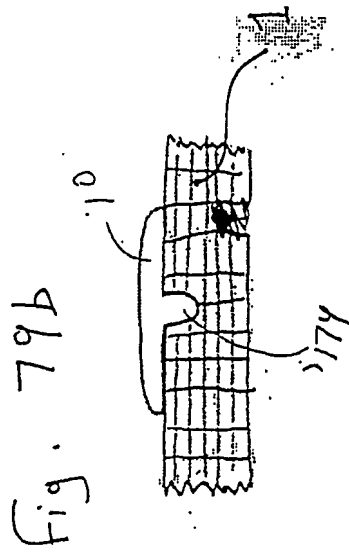
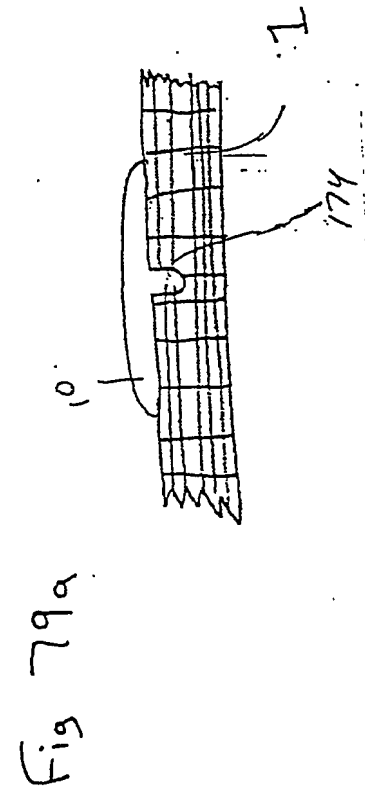


Fig. 80a

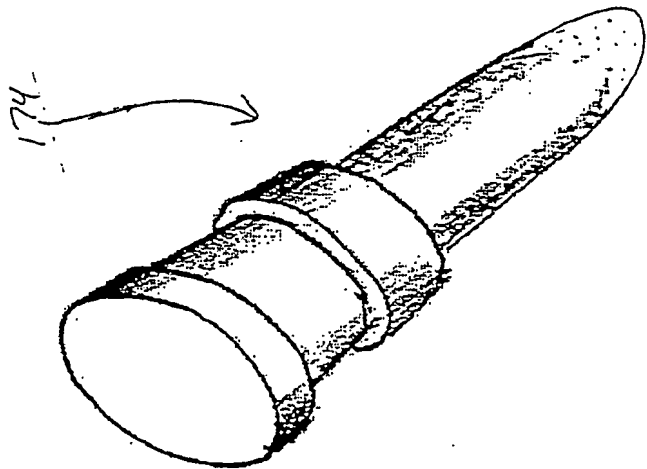
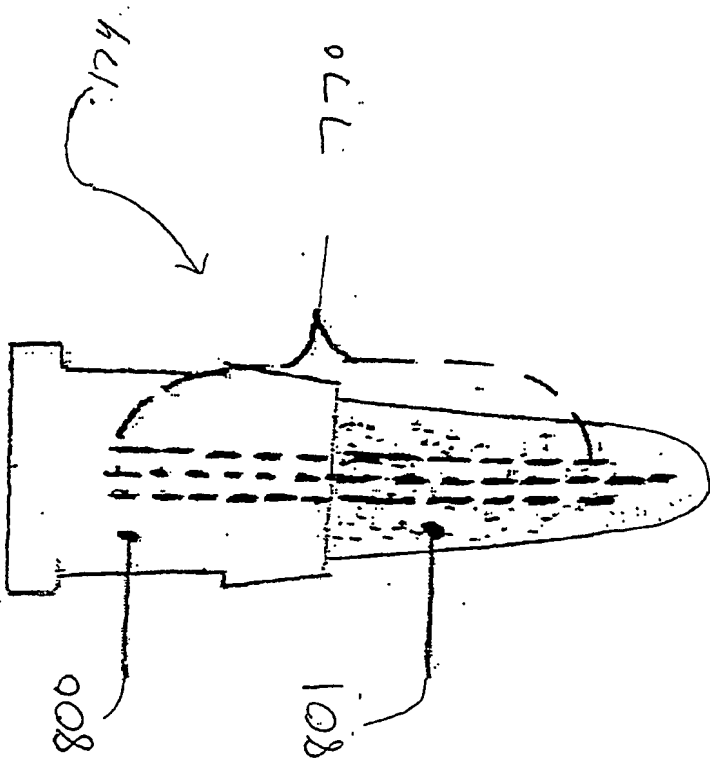


Fig. 80b



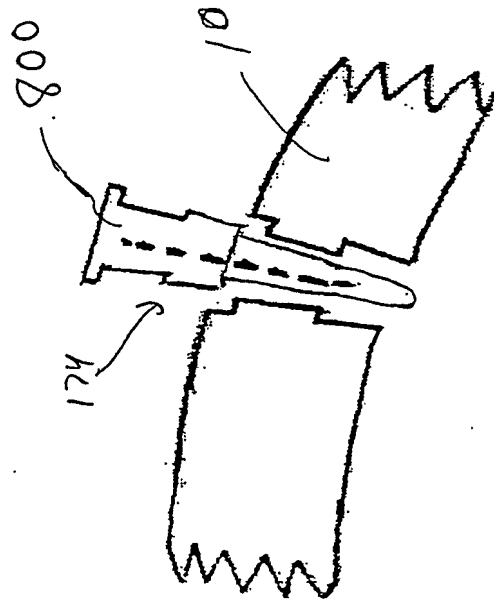


Fig. 81a

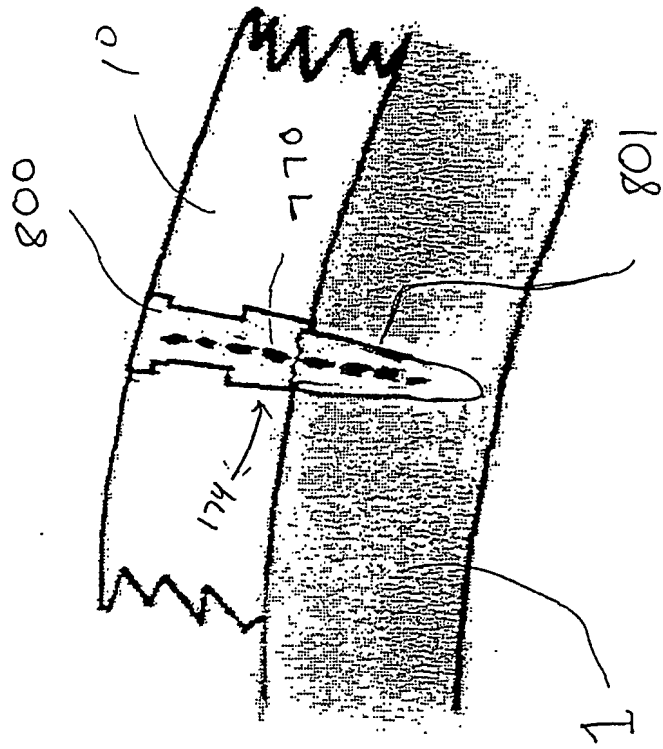


Fig. 81b

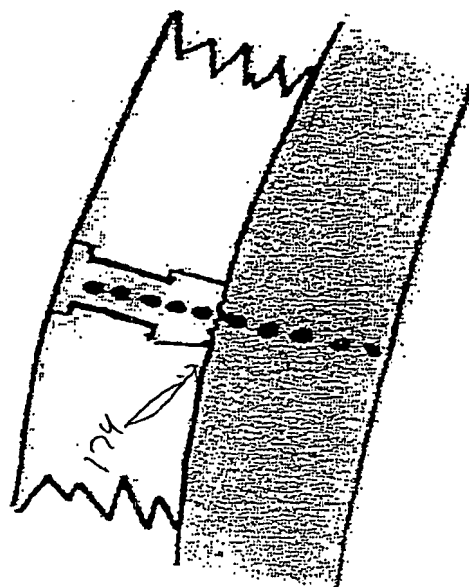


Fig. 82b

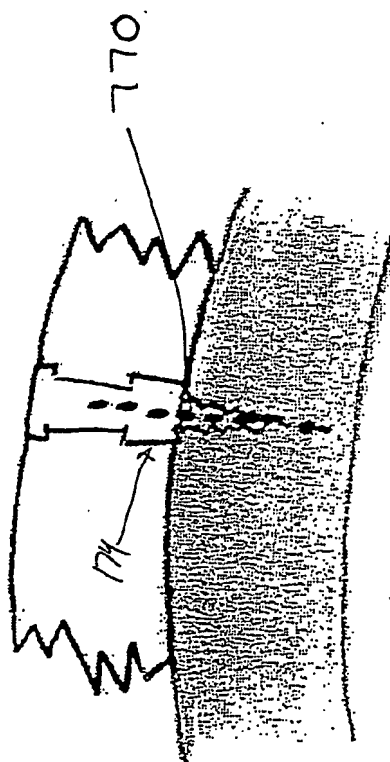


Fig. 82a



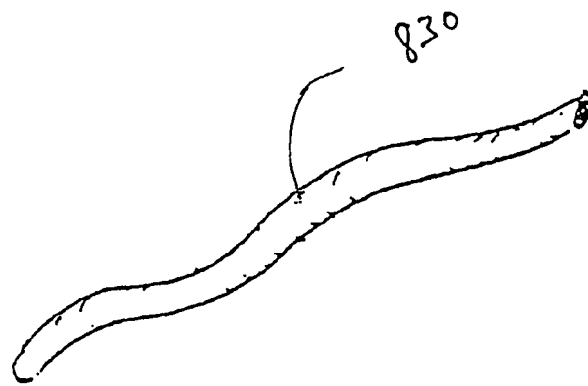


Fig. 83



Fig. 84a

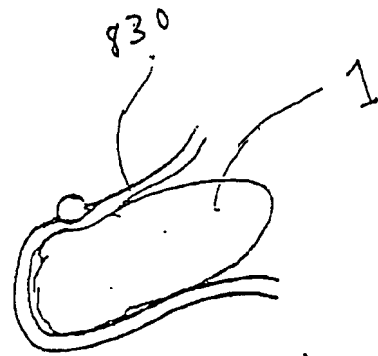


Fig. 84b

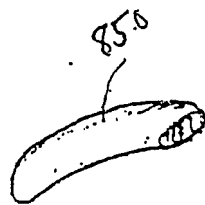


Fig. 85a



Fig. 85b

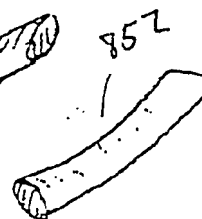


Fig. 85c

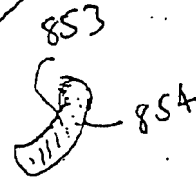
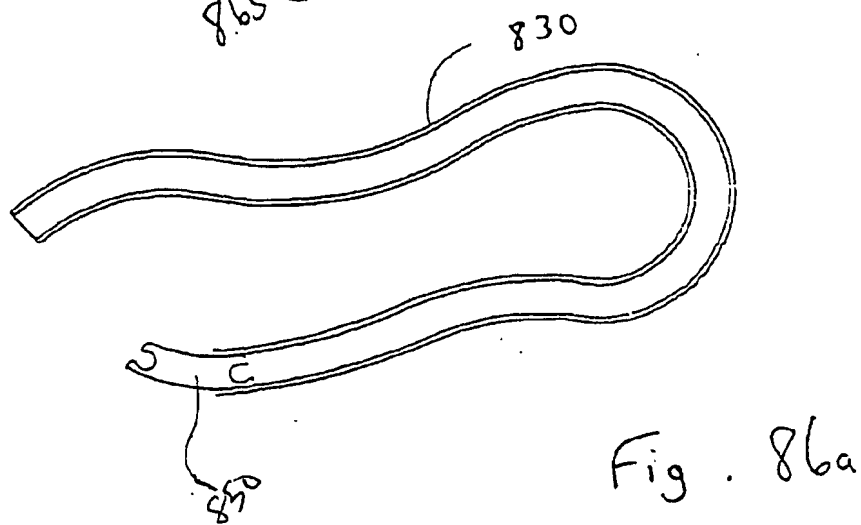
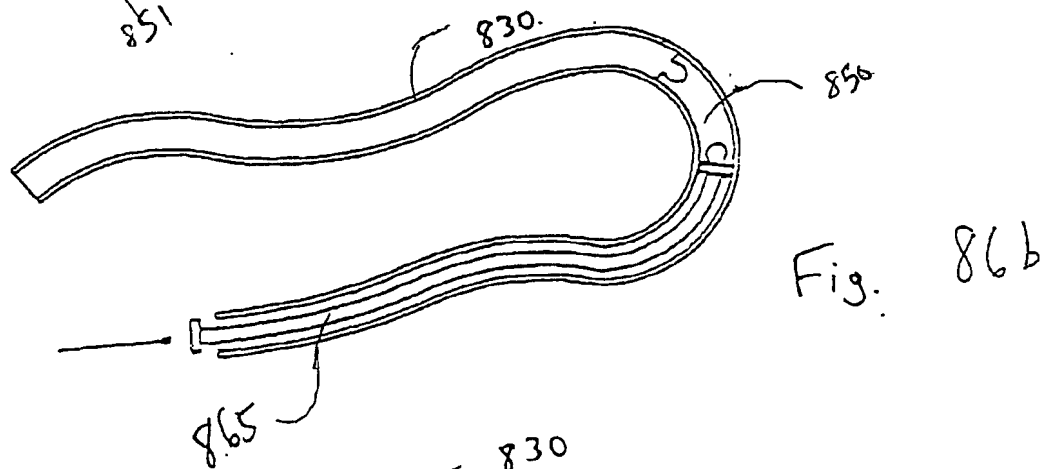
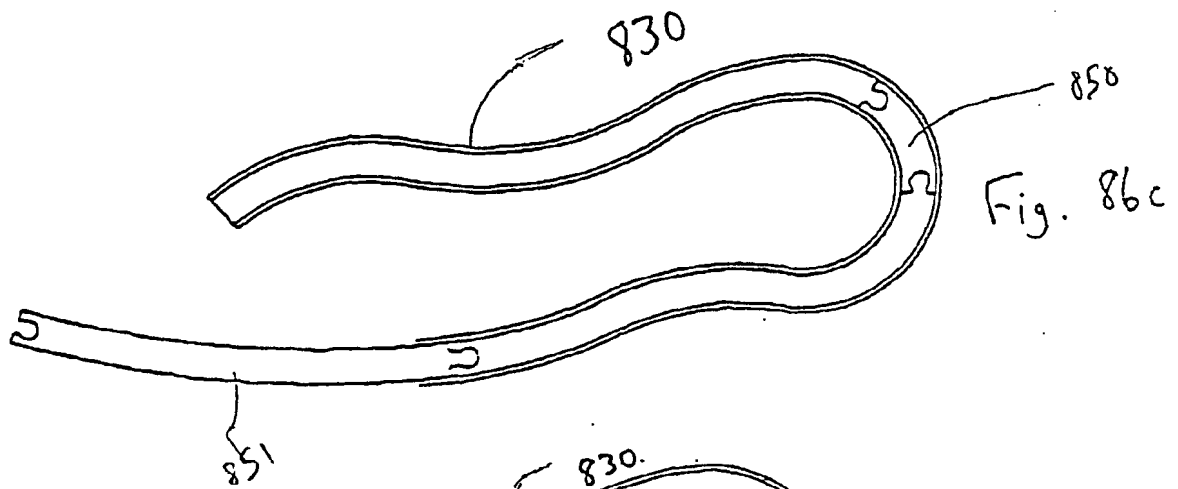


Fig. 85d



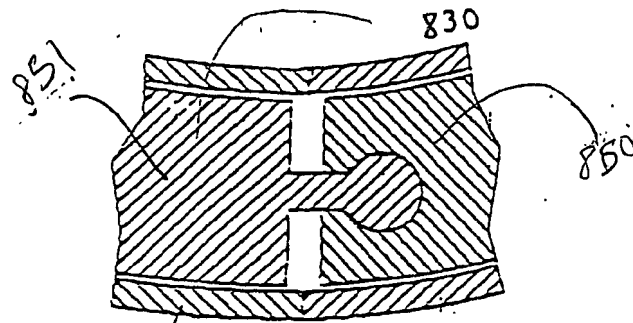


Fig. 86f

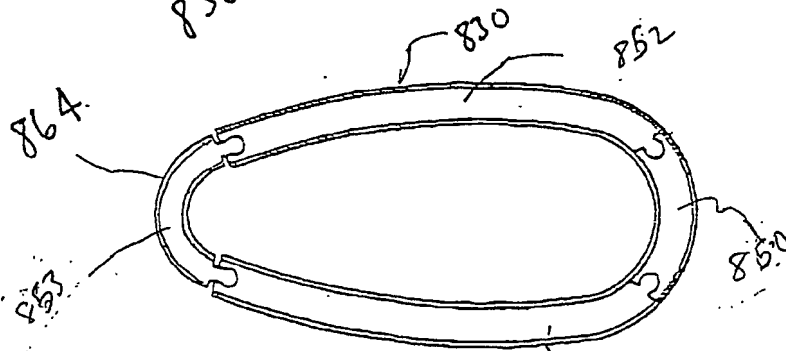


Fig. 86e

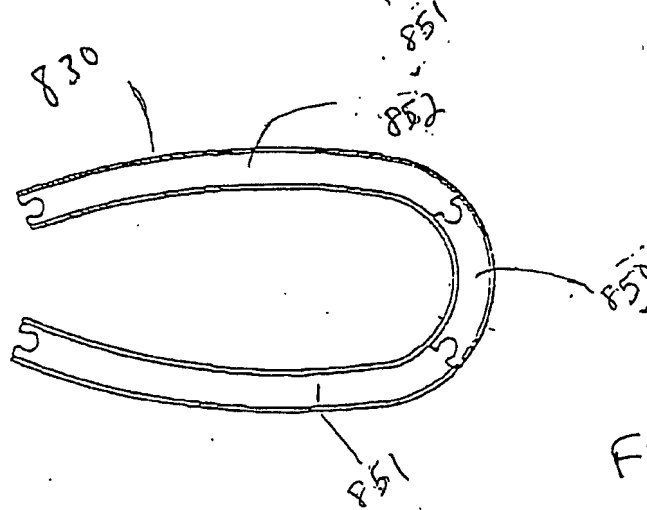


Fig. 86d

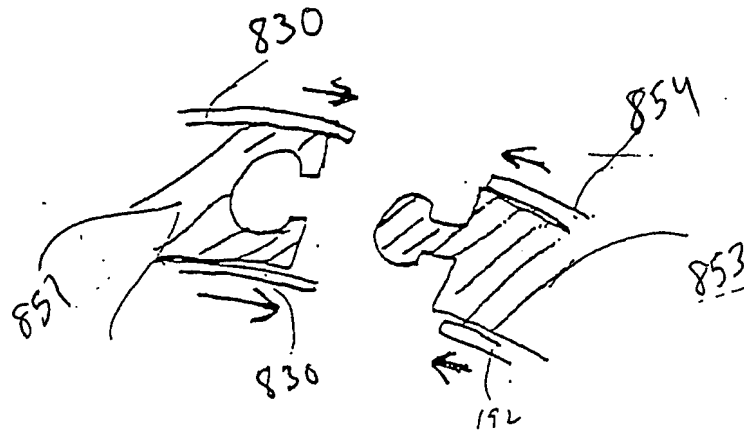


Fig. 86g

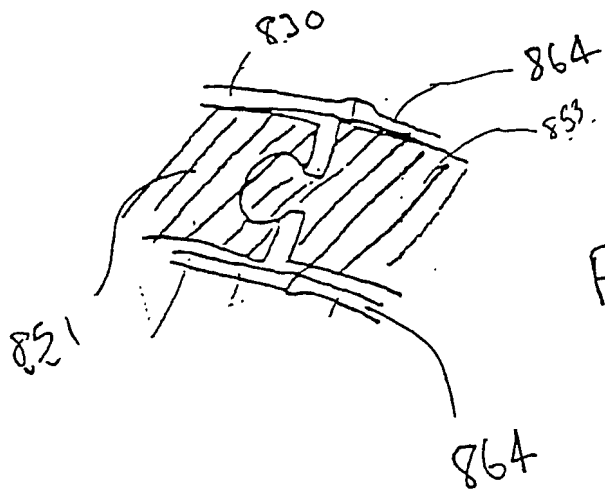


Fig. 86h

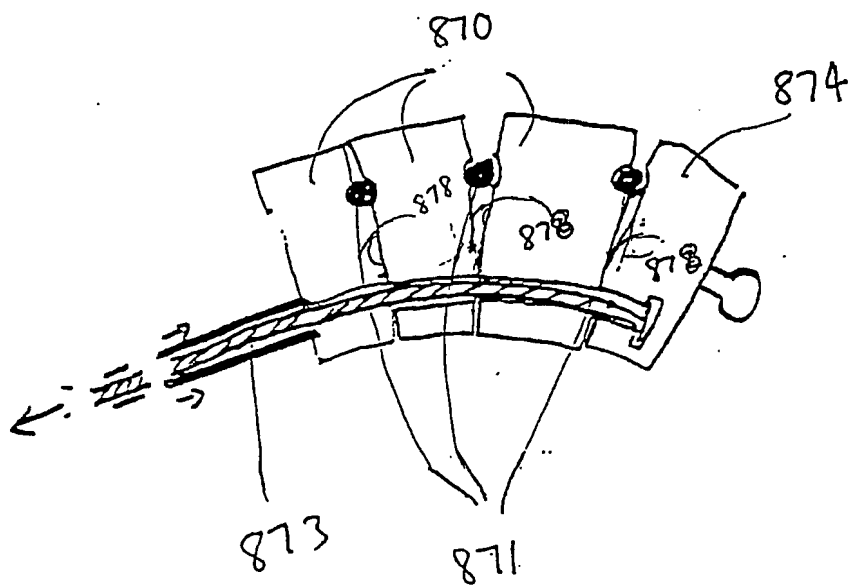


Fig. 87

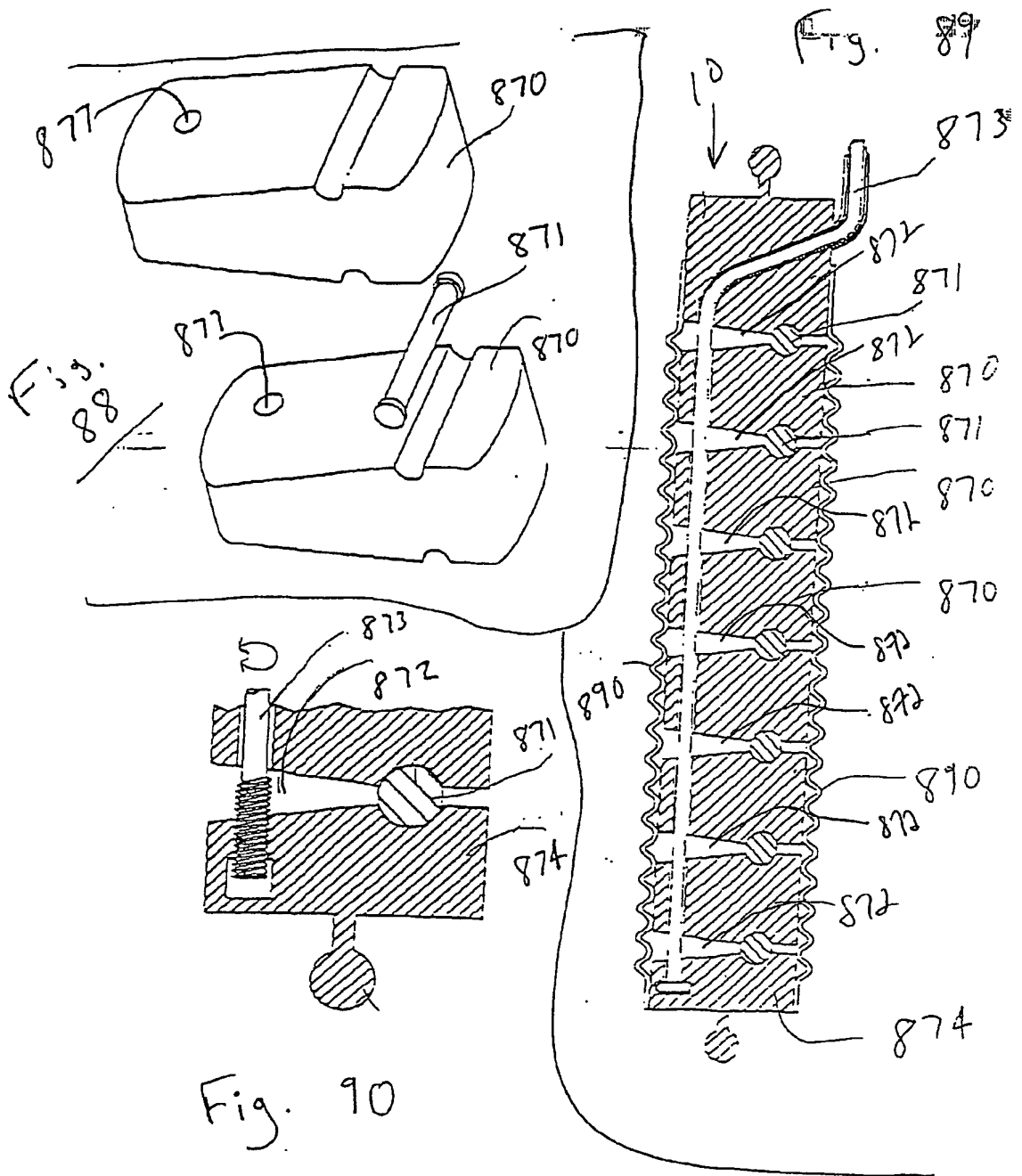


Fig 94

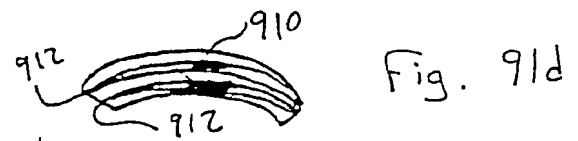
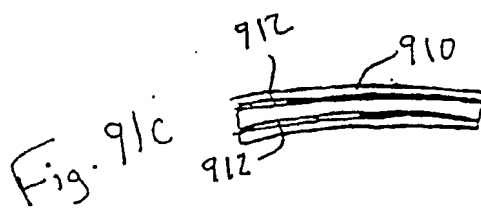
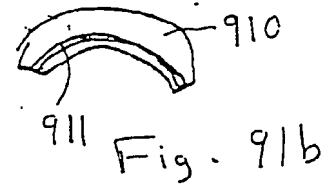
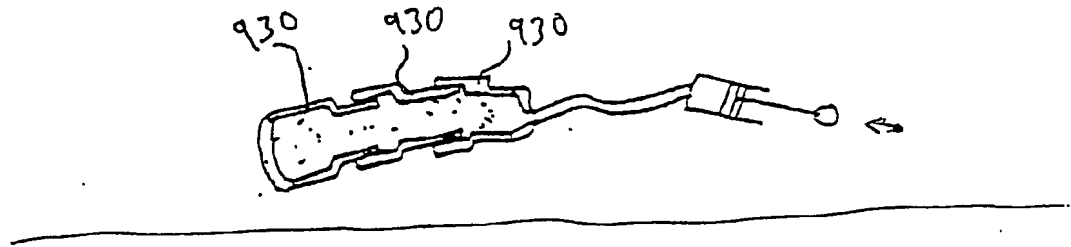


Fig. 93a

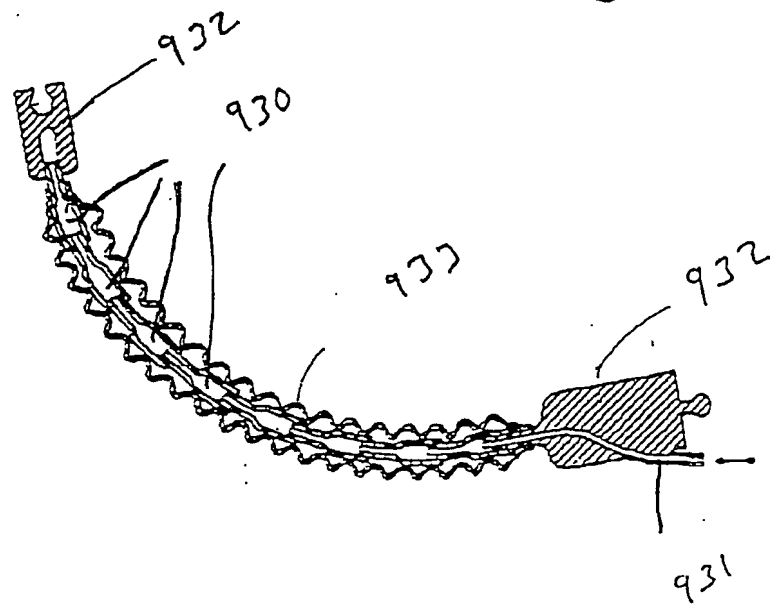
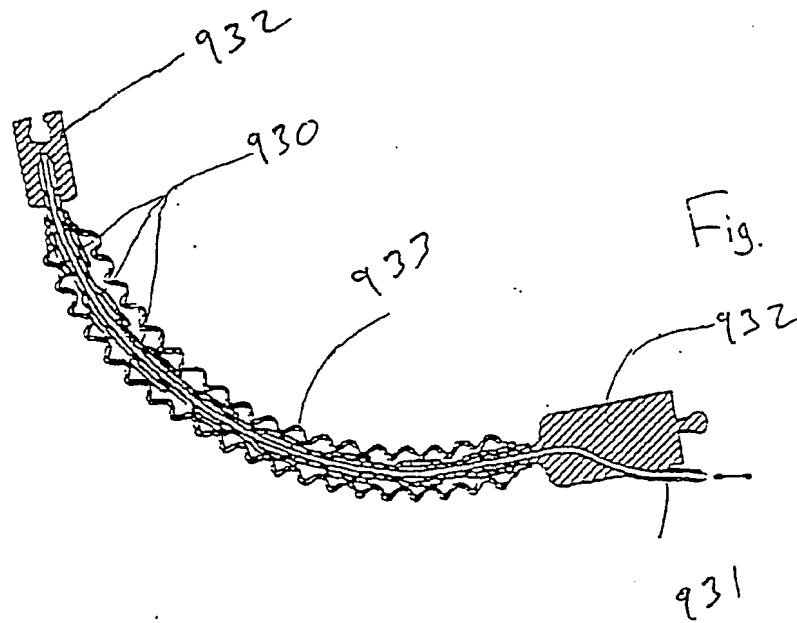
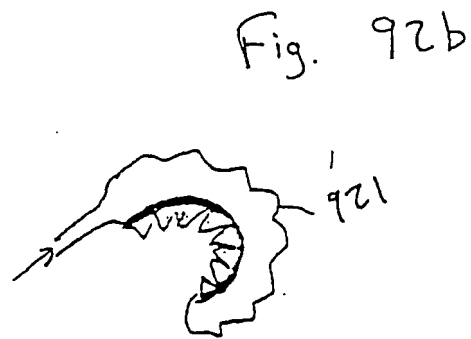
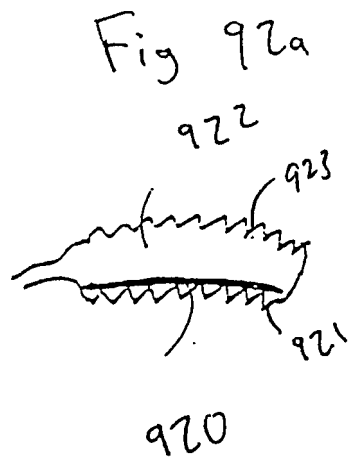
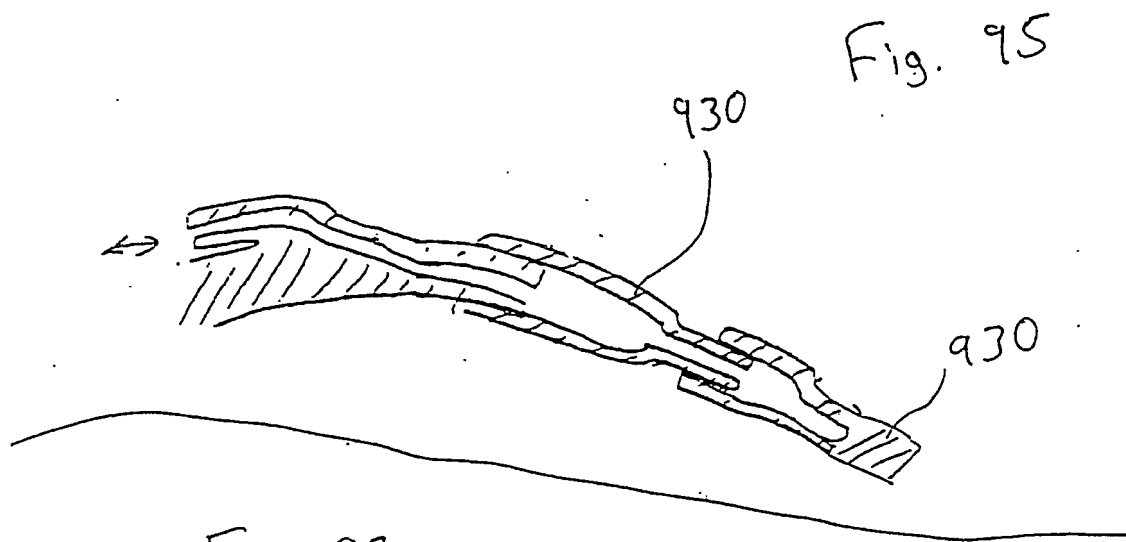
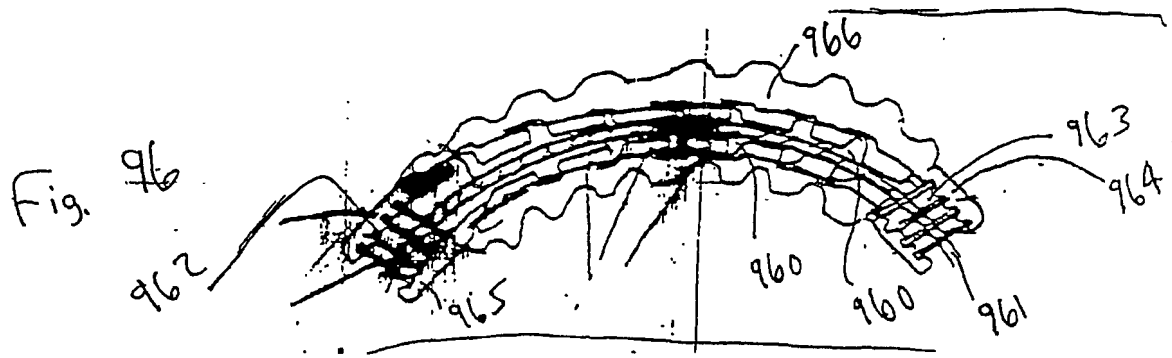


Fig. 93b









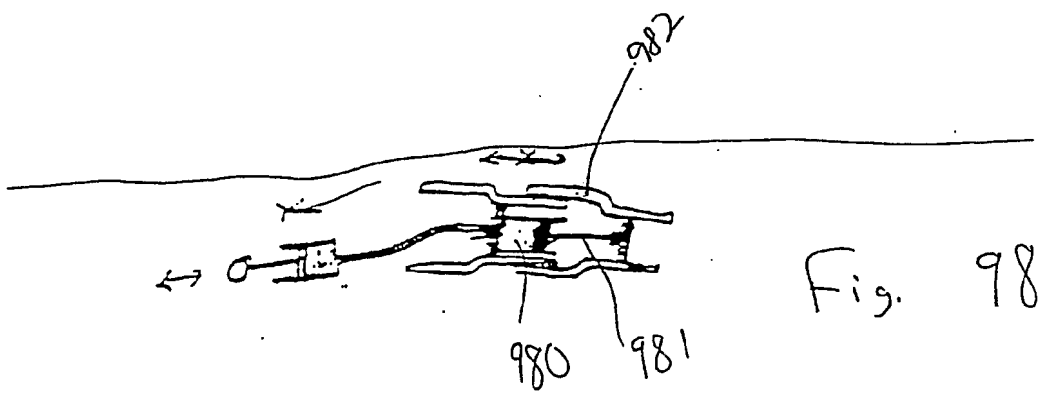
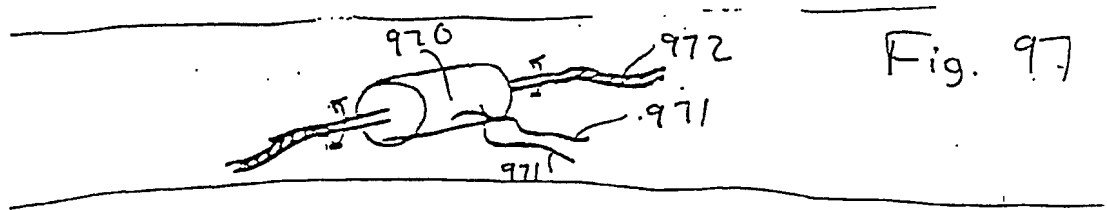


Fig. 99  
a.

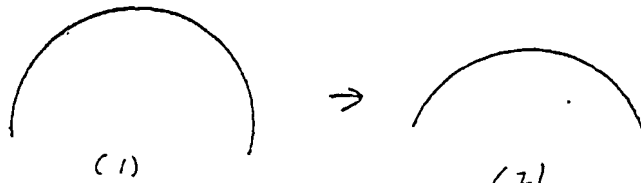


Fig 99b

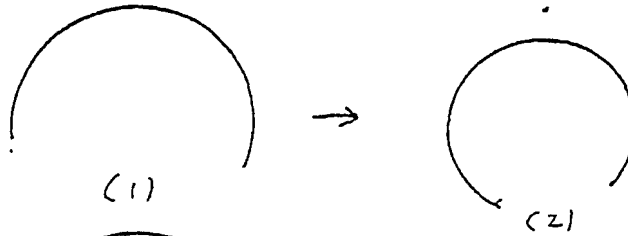


Fig. 99C

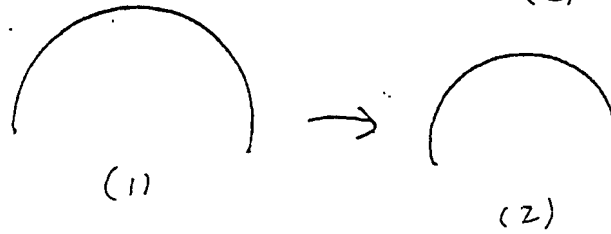




Fig. 100

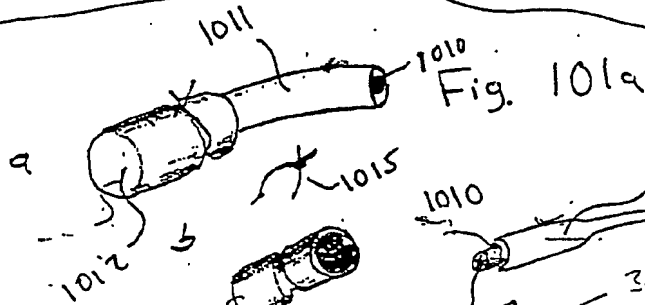


Fig. 101a

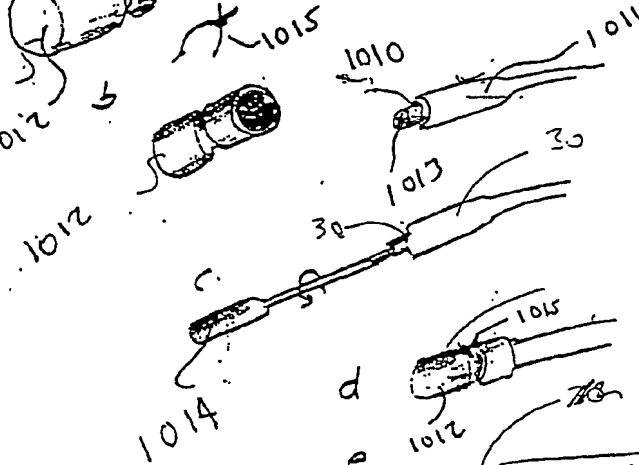


Fig. 101b

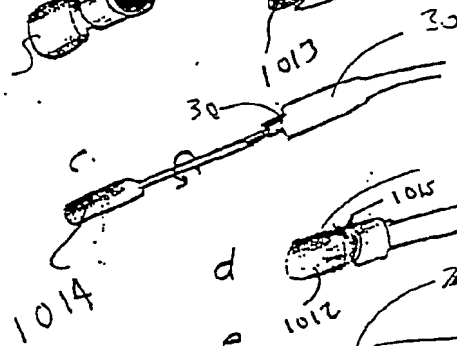


Fig. 101c

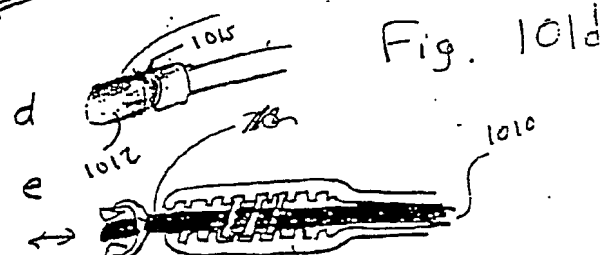


Fig. 101d

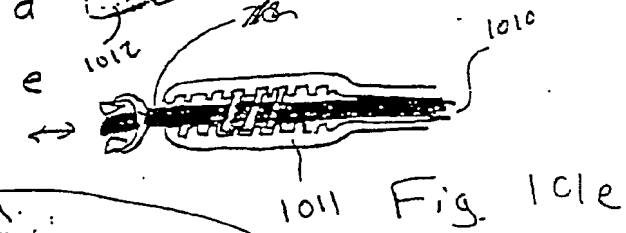


Fig. 101e

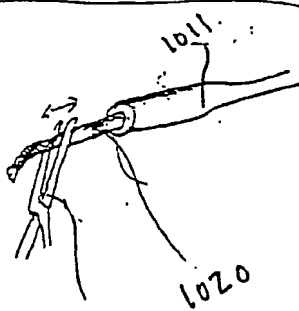


Fig. 102

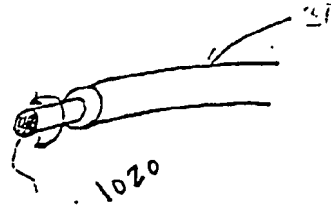


Fig. 103  
PCT/US 01/17637

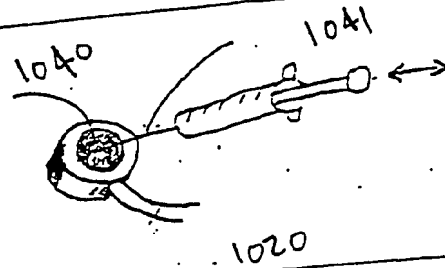


Fig. 104



Fig. 105a

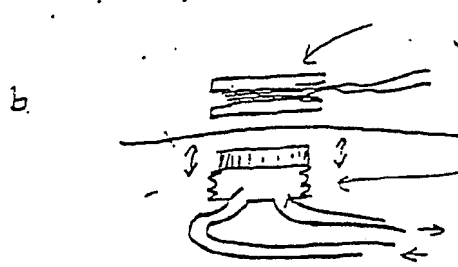
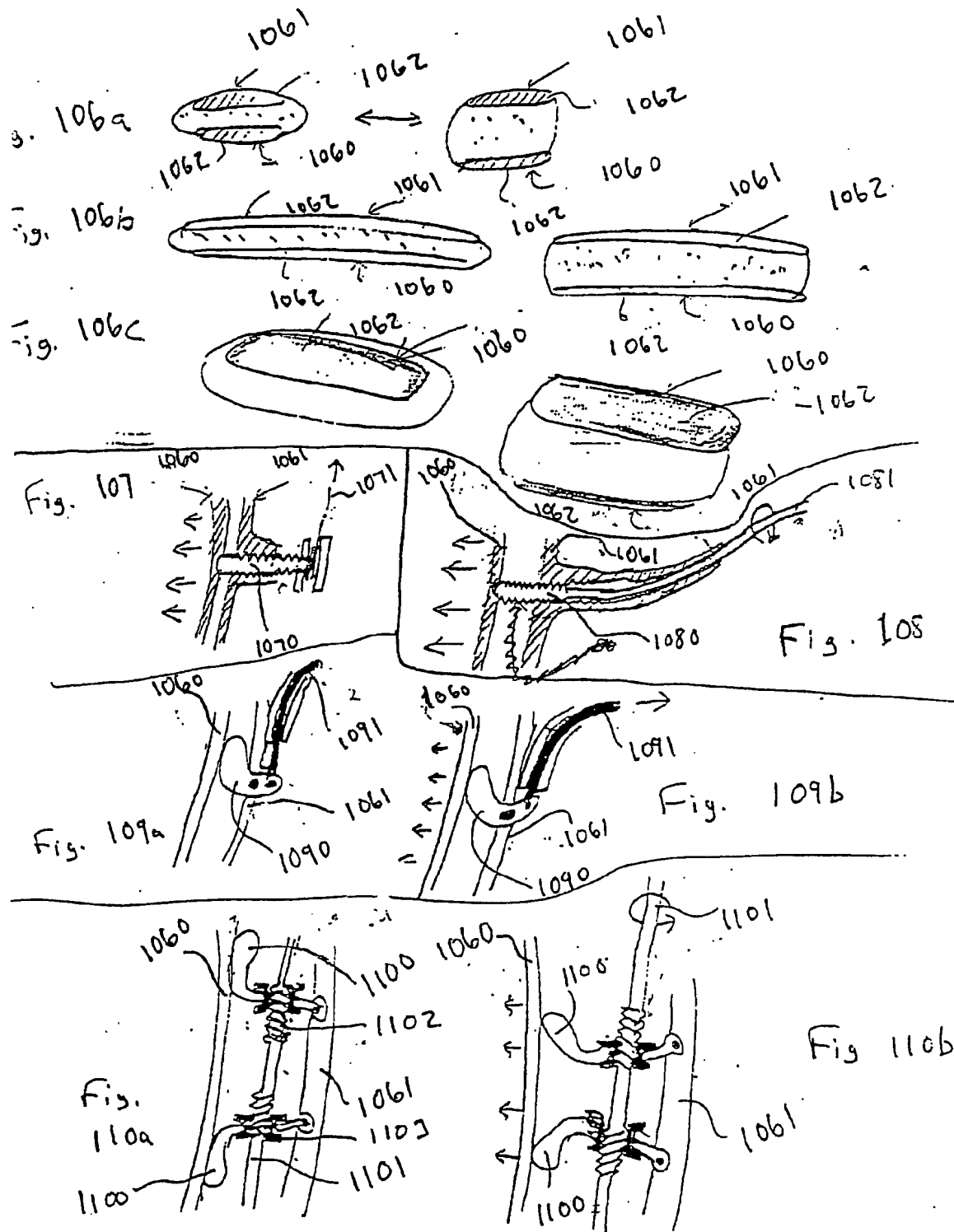
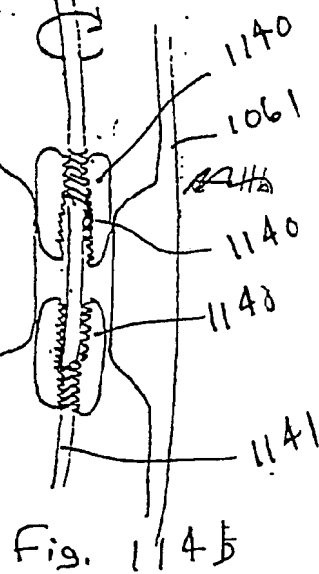
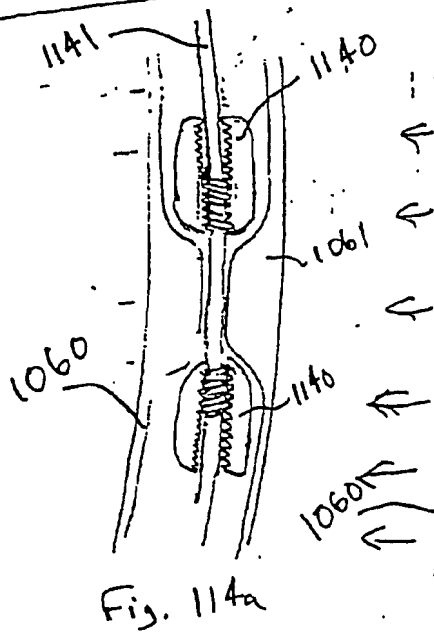
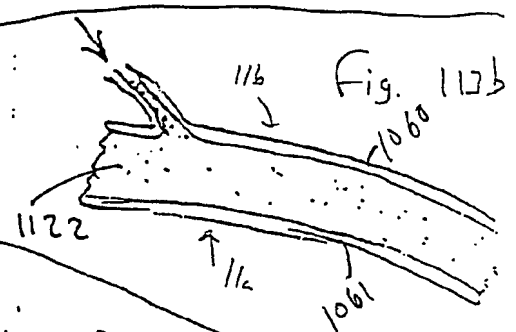
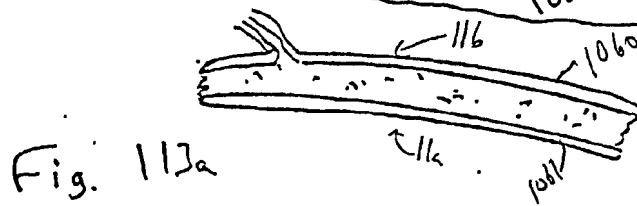
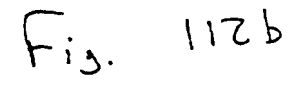
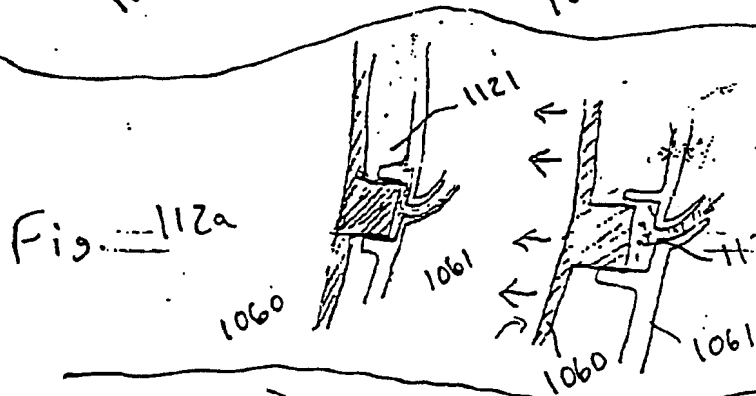
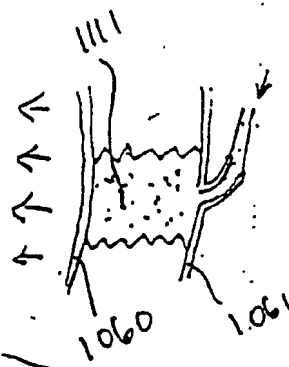
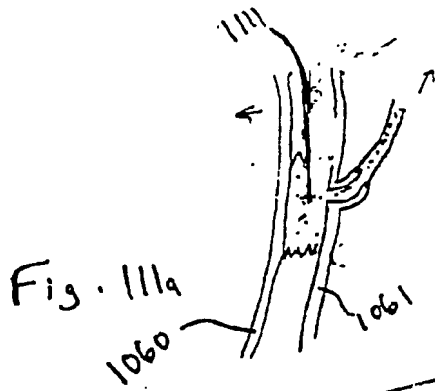
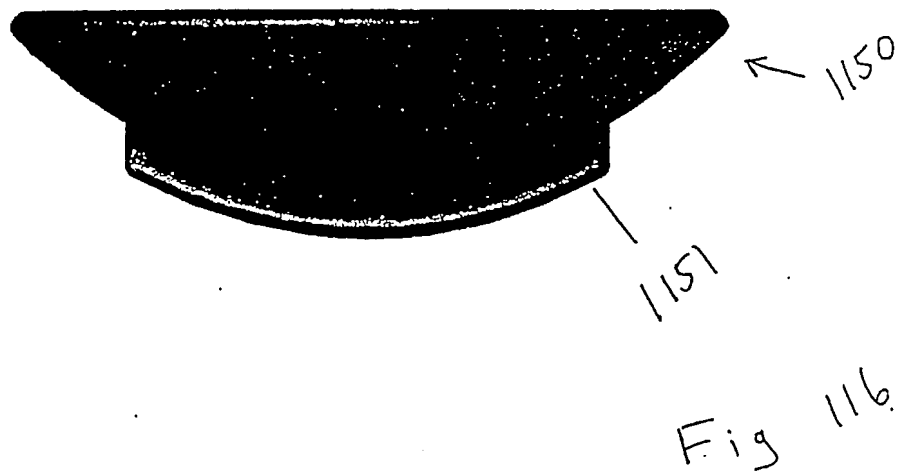
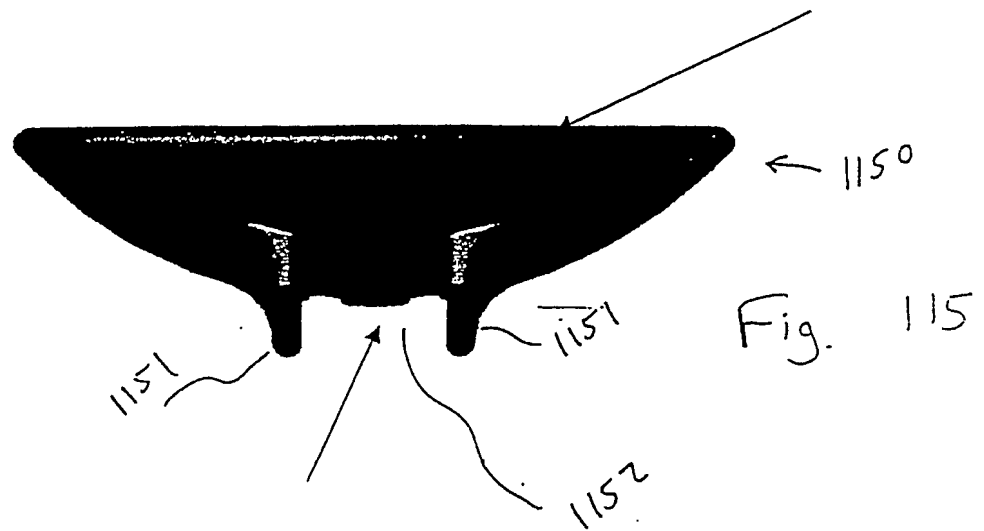


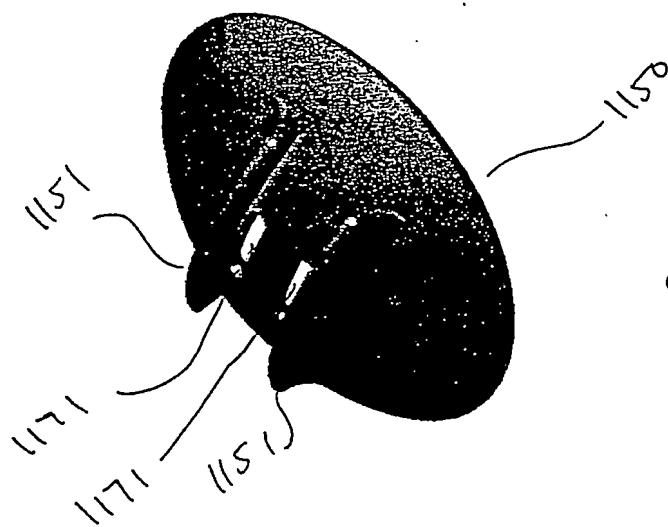
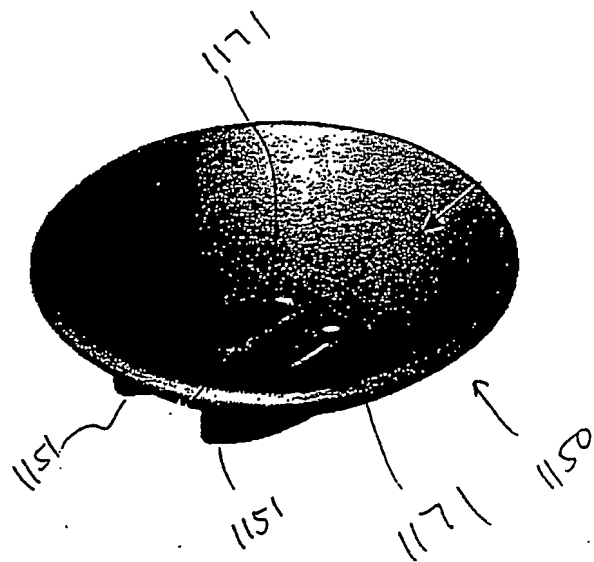
Fig. 105b











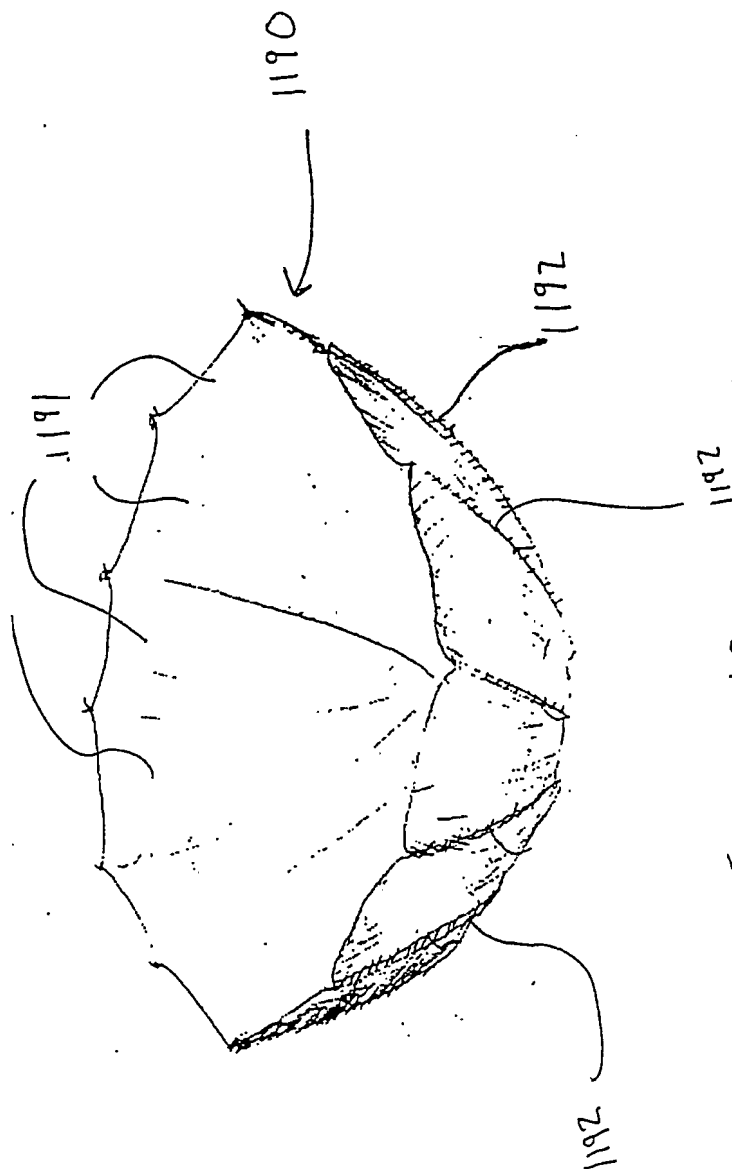
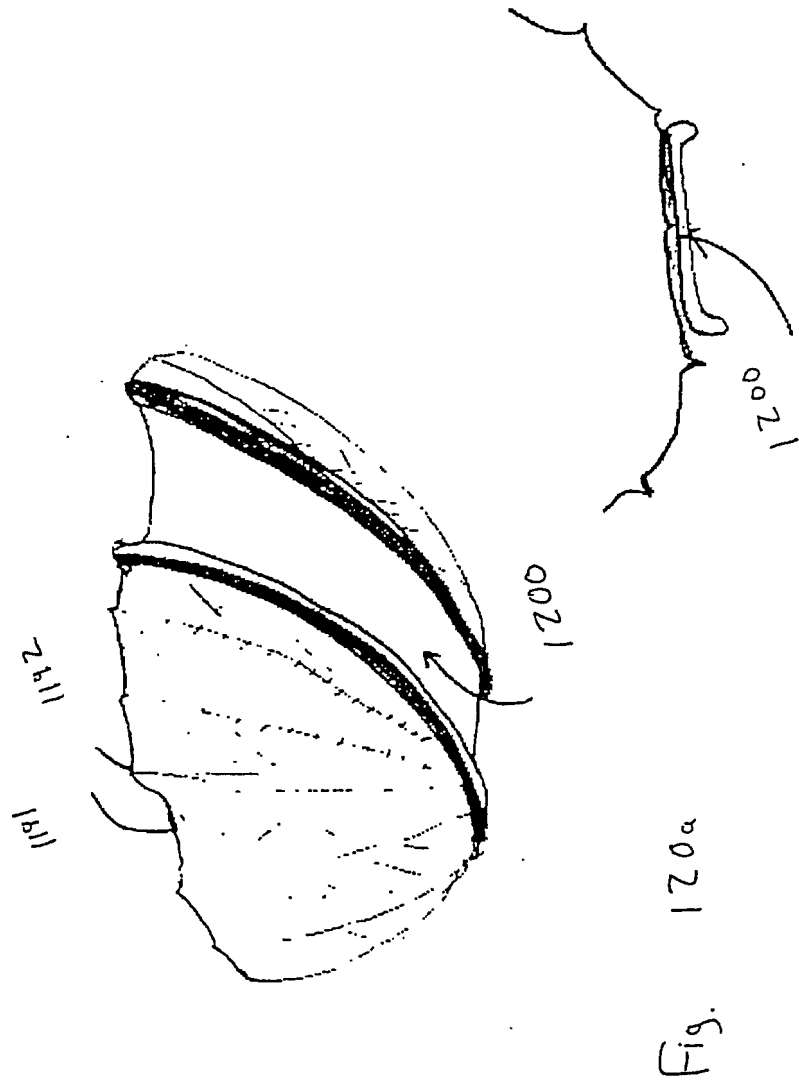


Fig. 119



0121

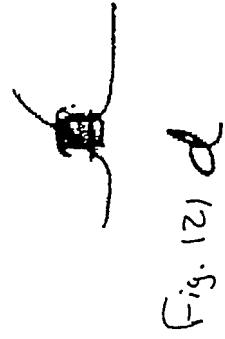


Fig. 121d

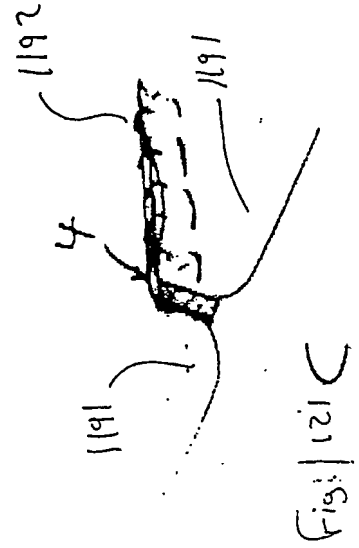


Fig. 121c

Fig. 121a



Fig. 121b

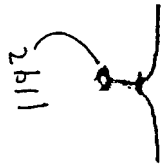


Fig. 122

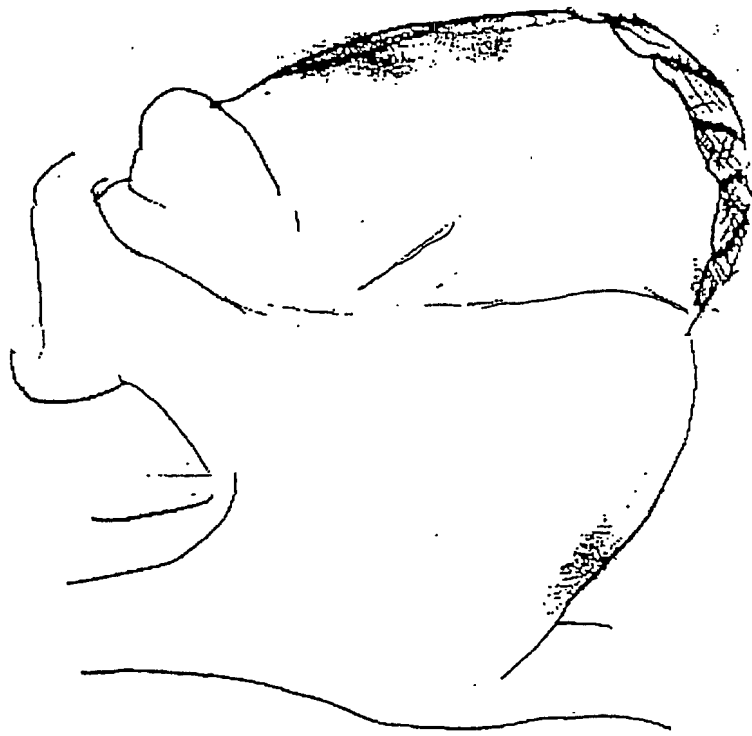
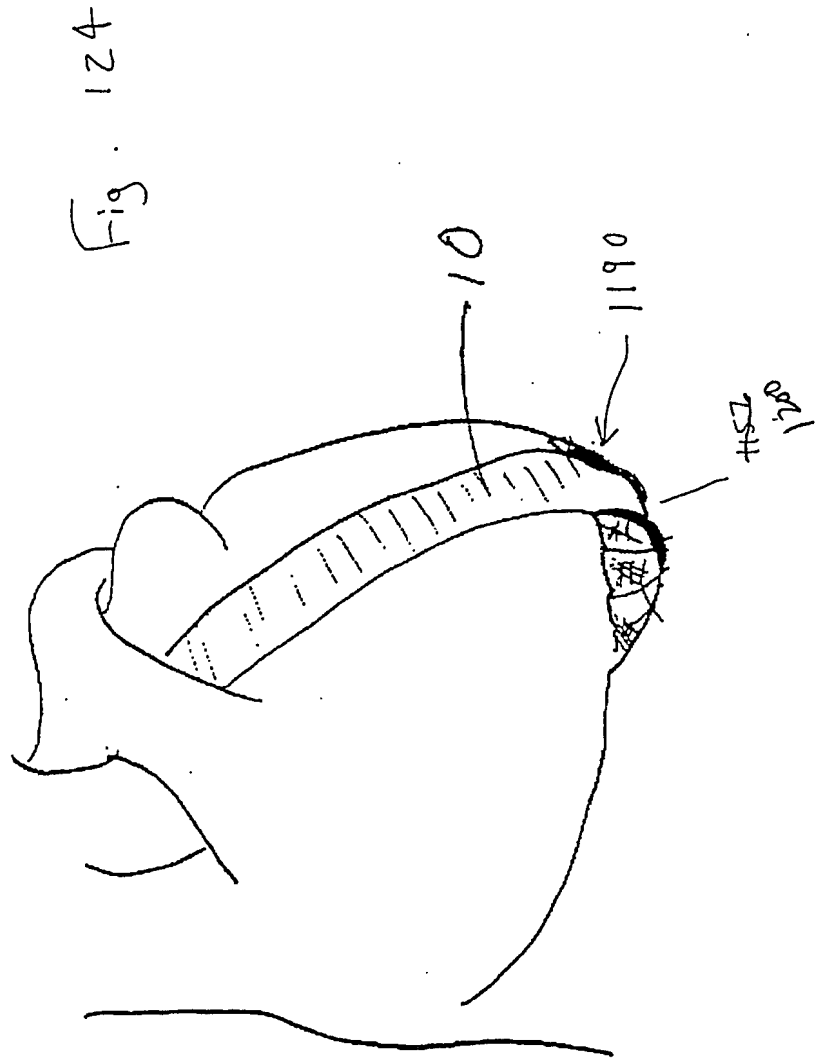


Fig. 123







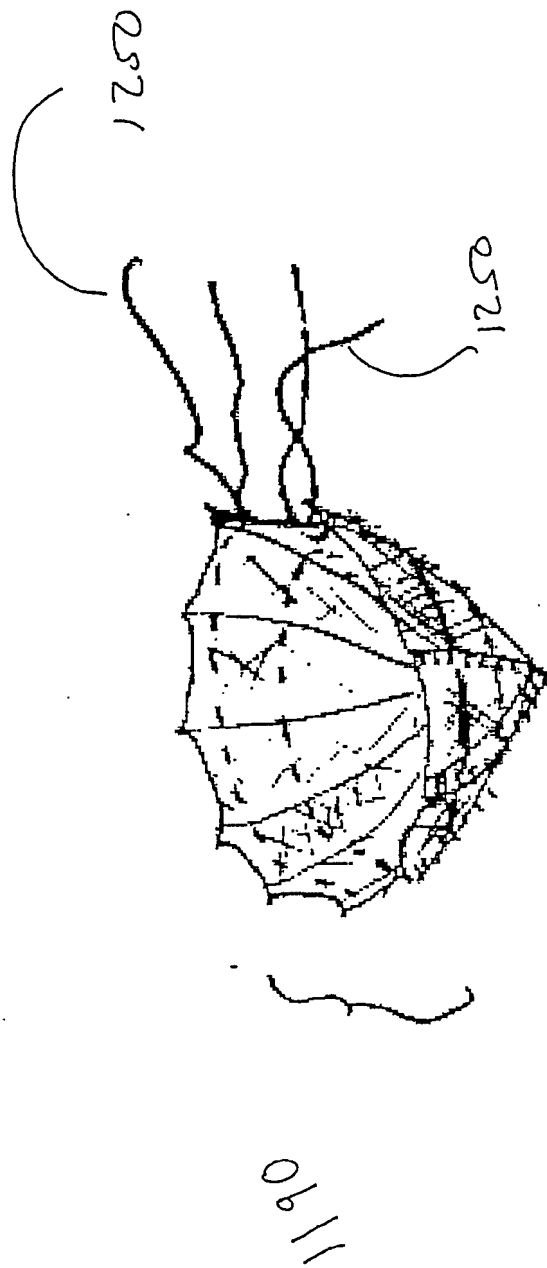


Fig. 125

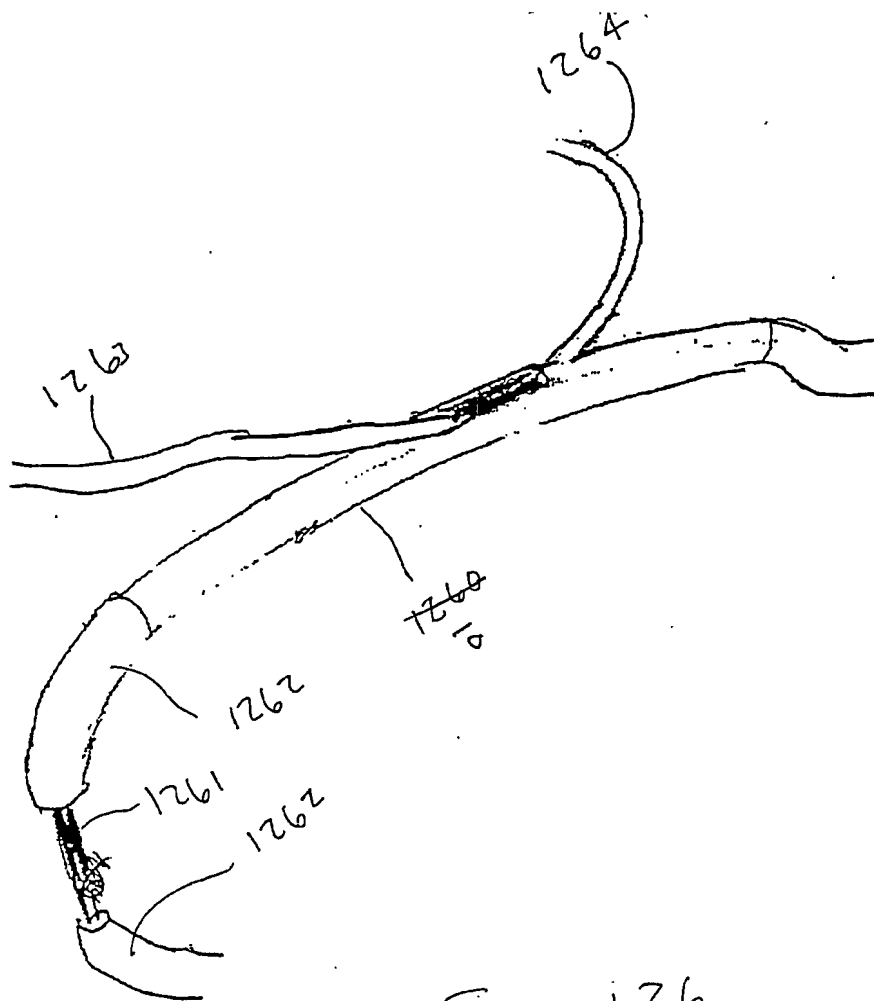


Fig. 126

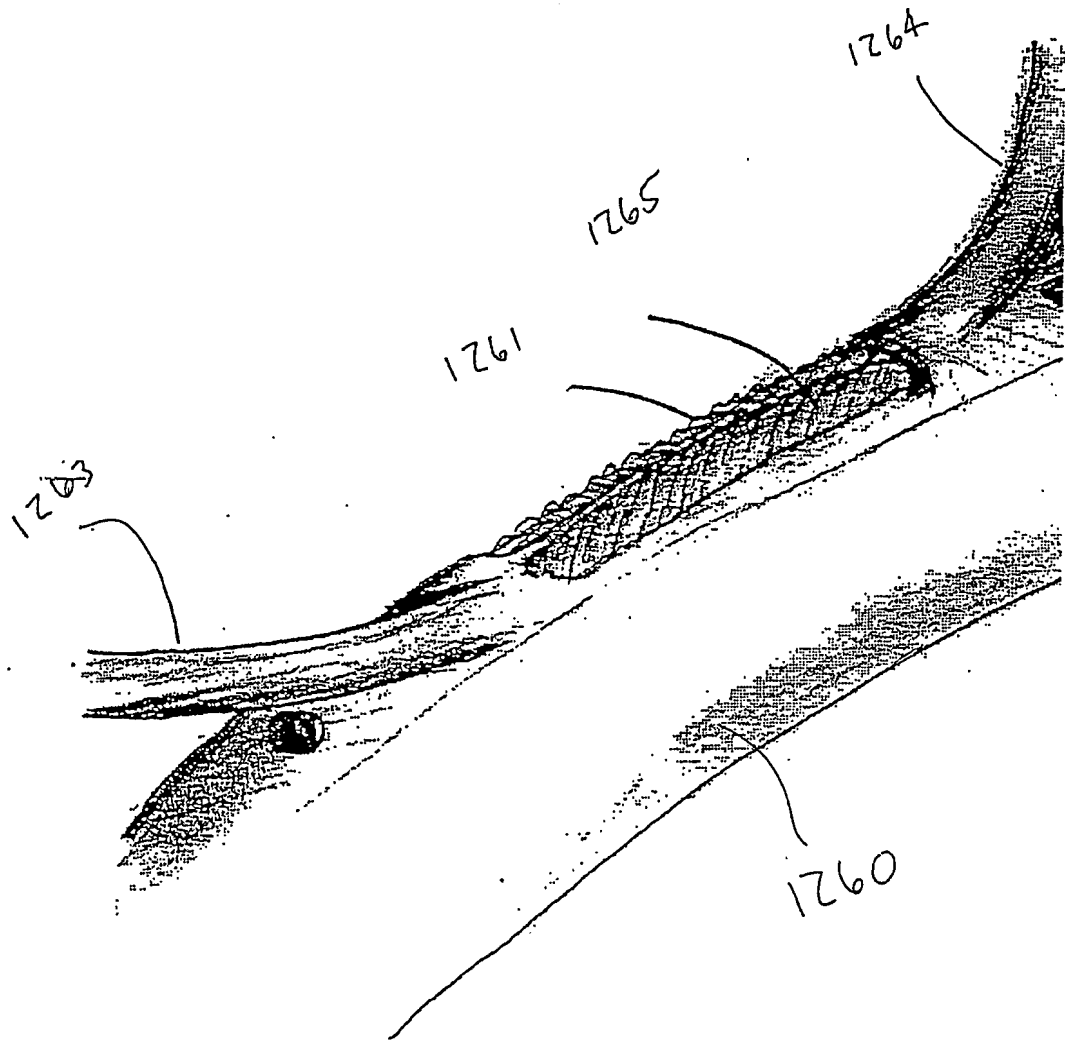


Fig 127

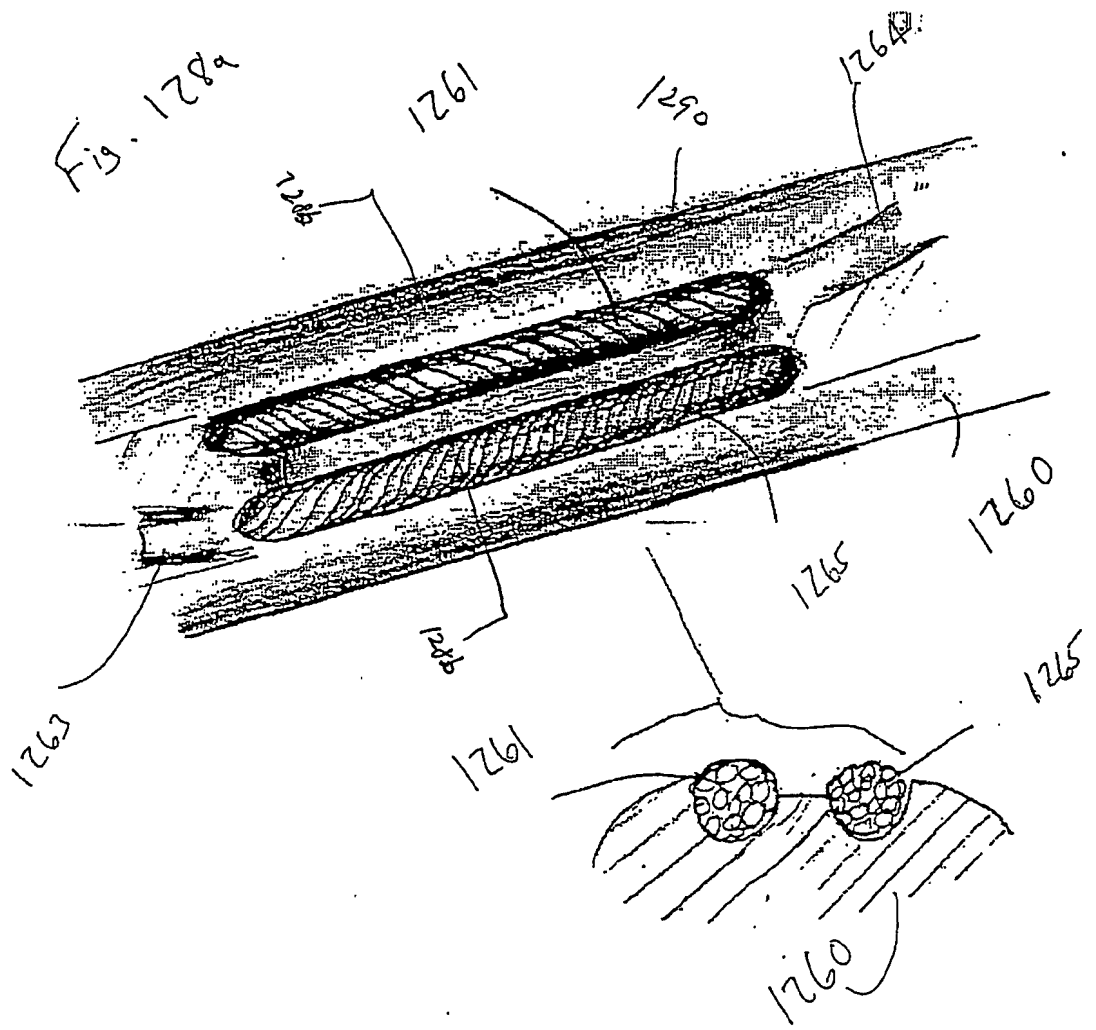


Fig. 128b

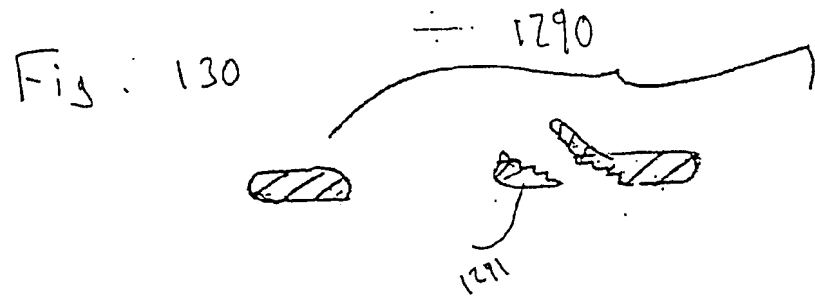
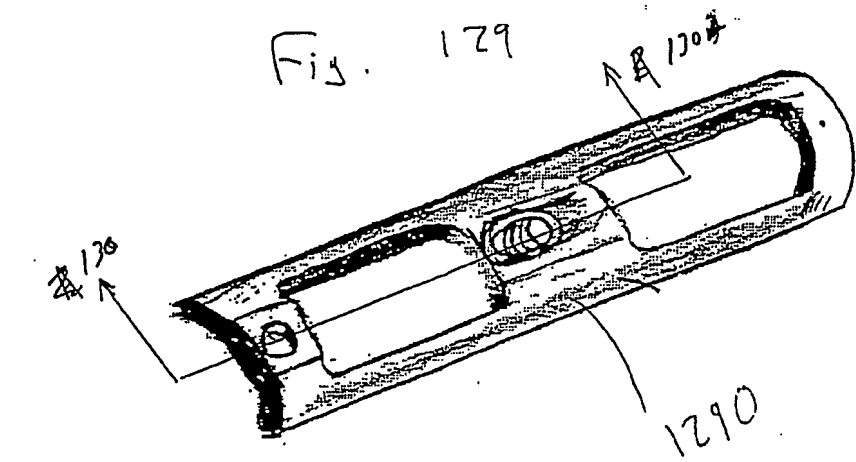
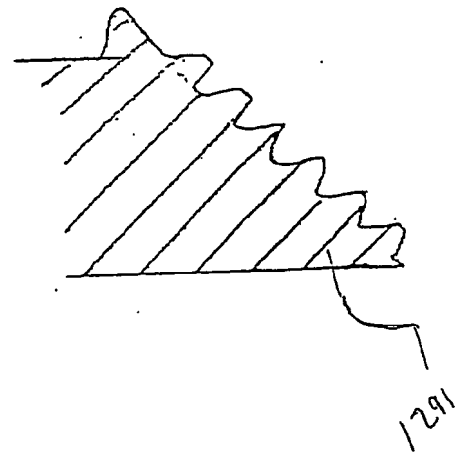
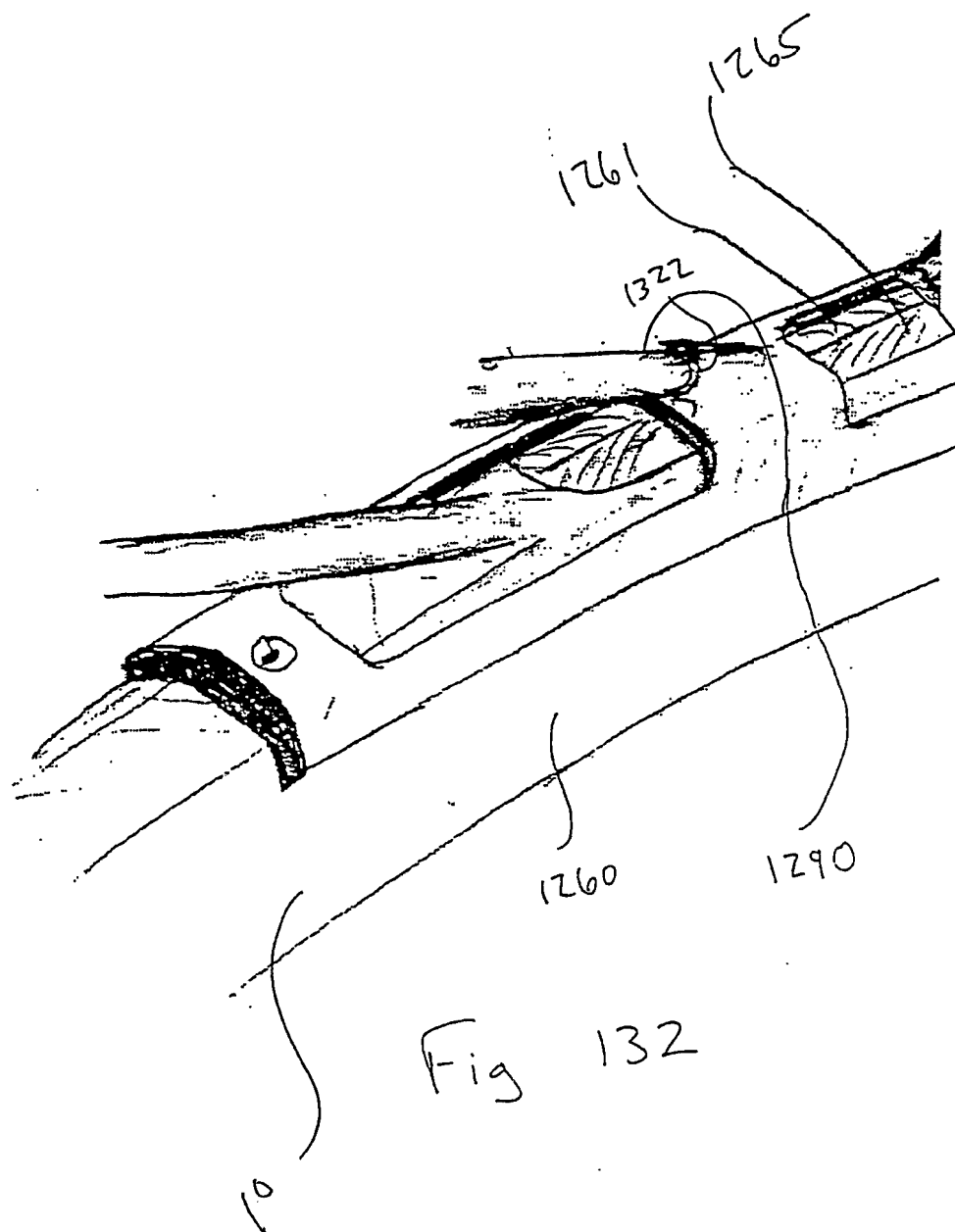


Fig. 131





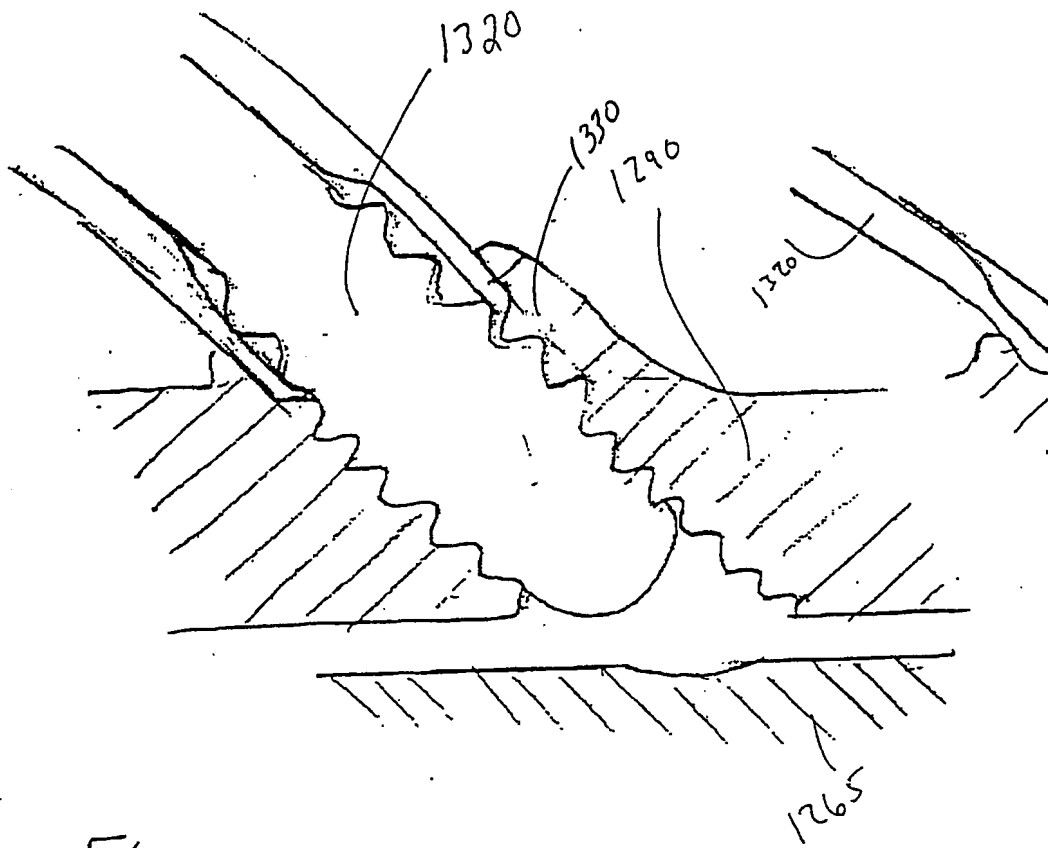
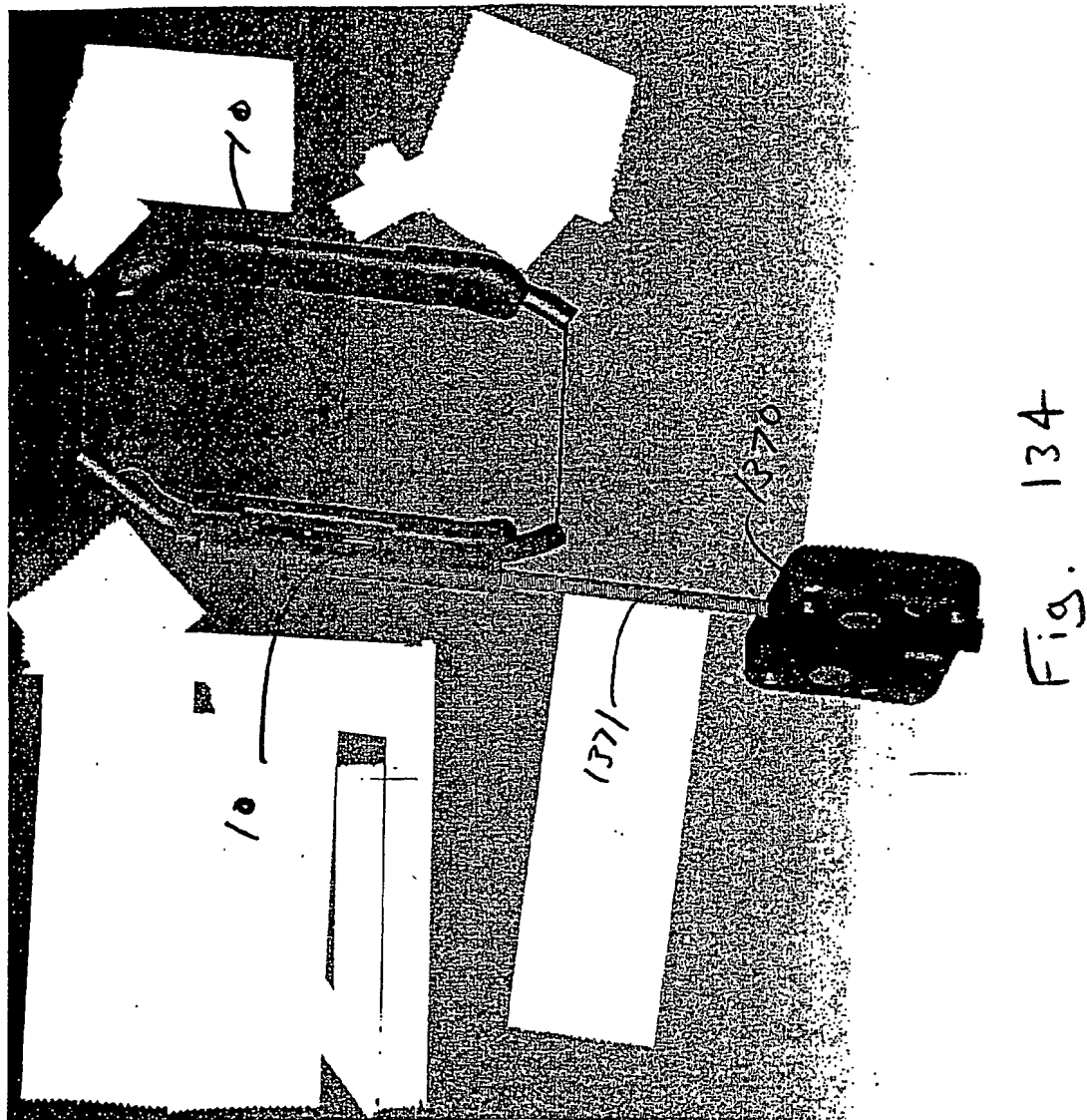
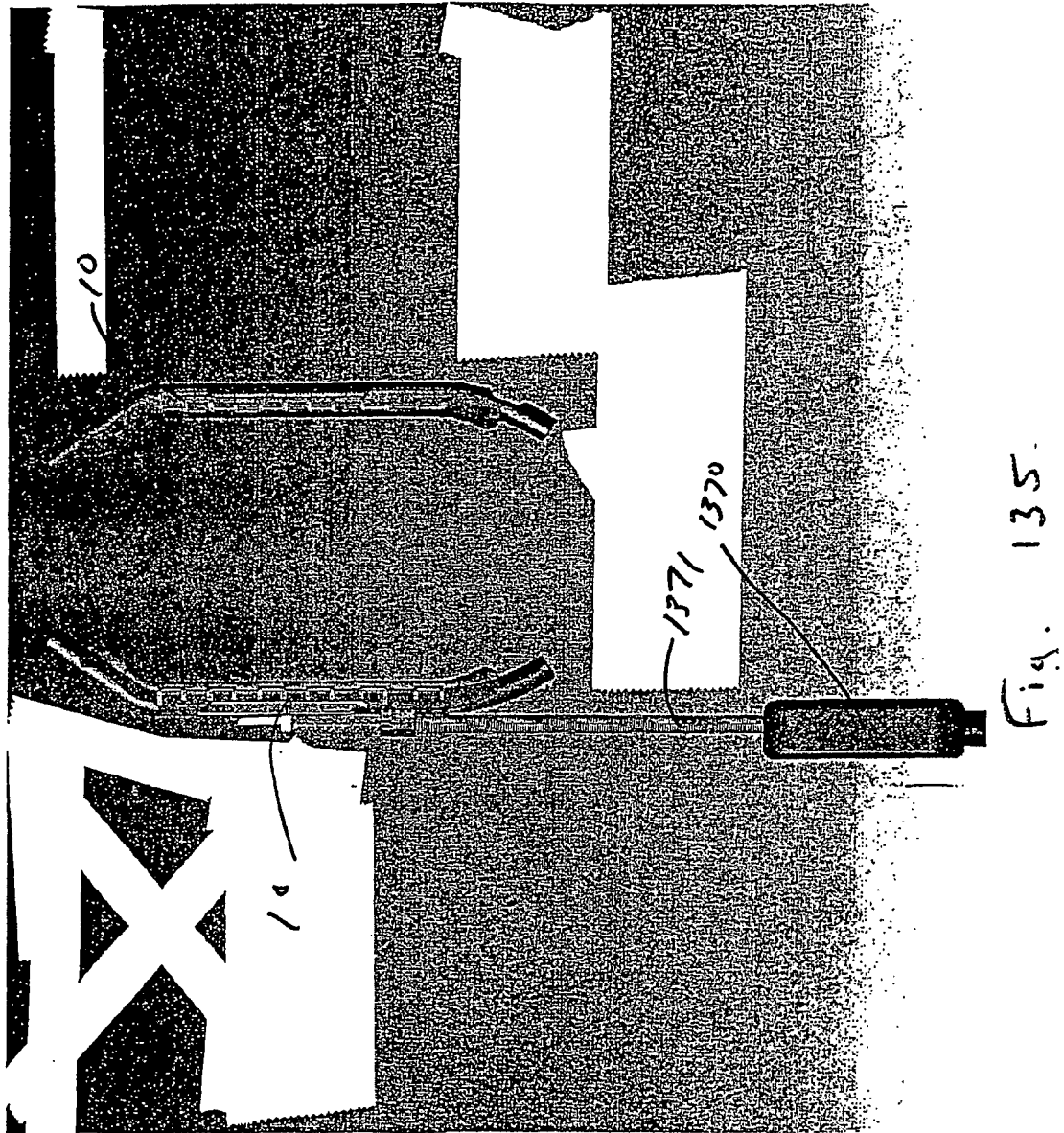


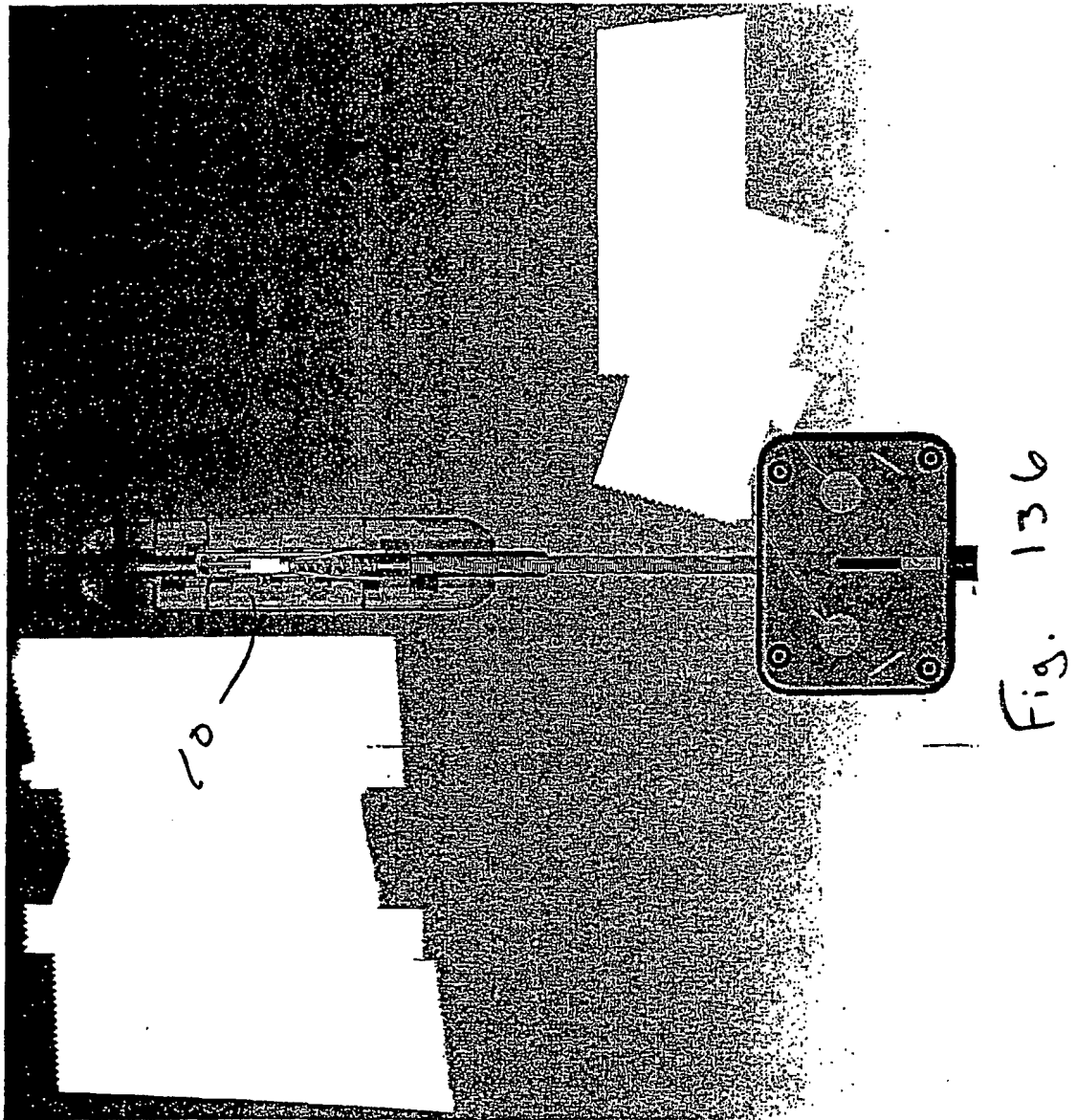
FIG.

133









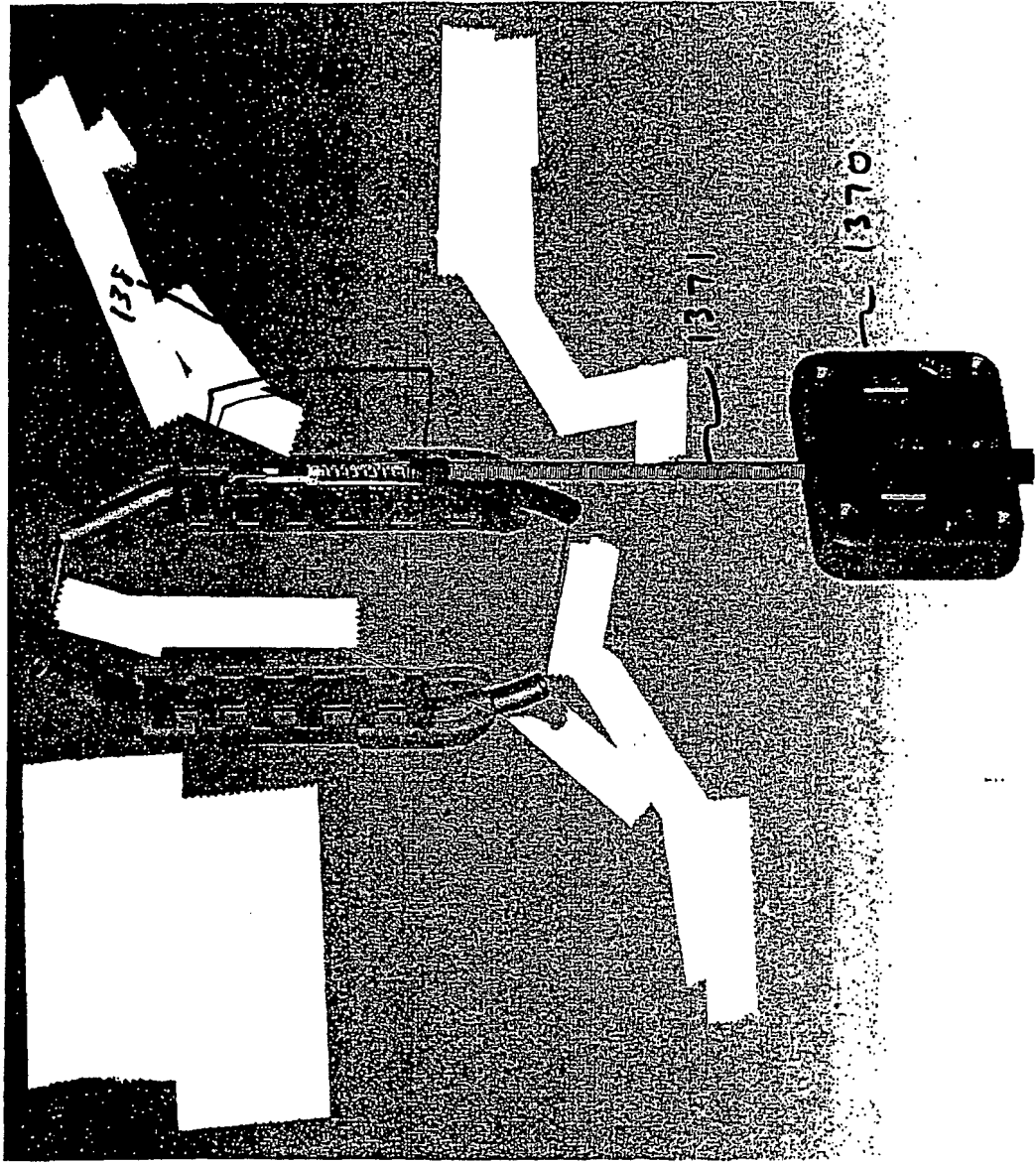


Fig. 137

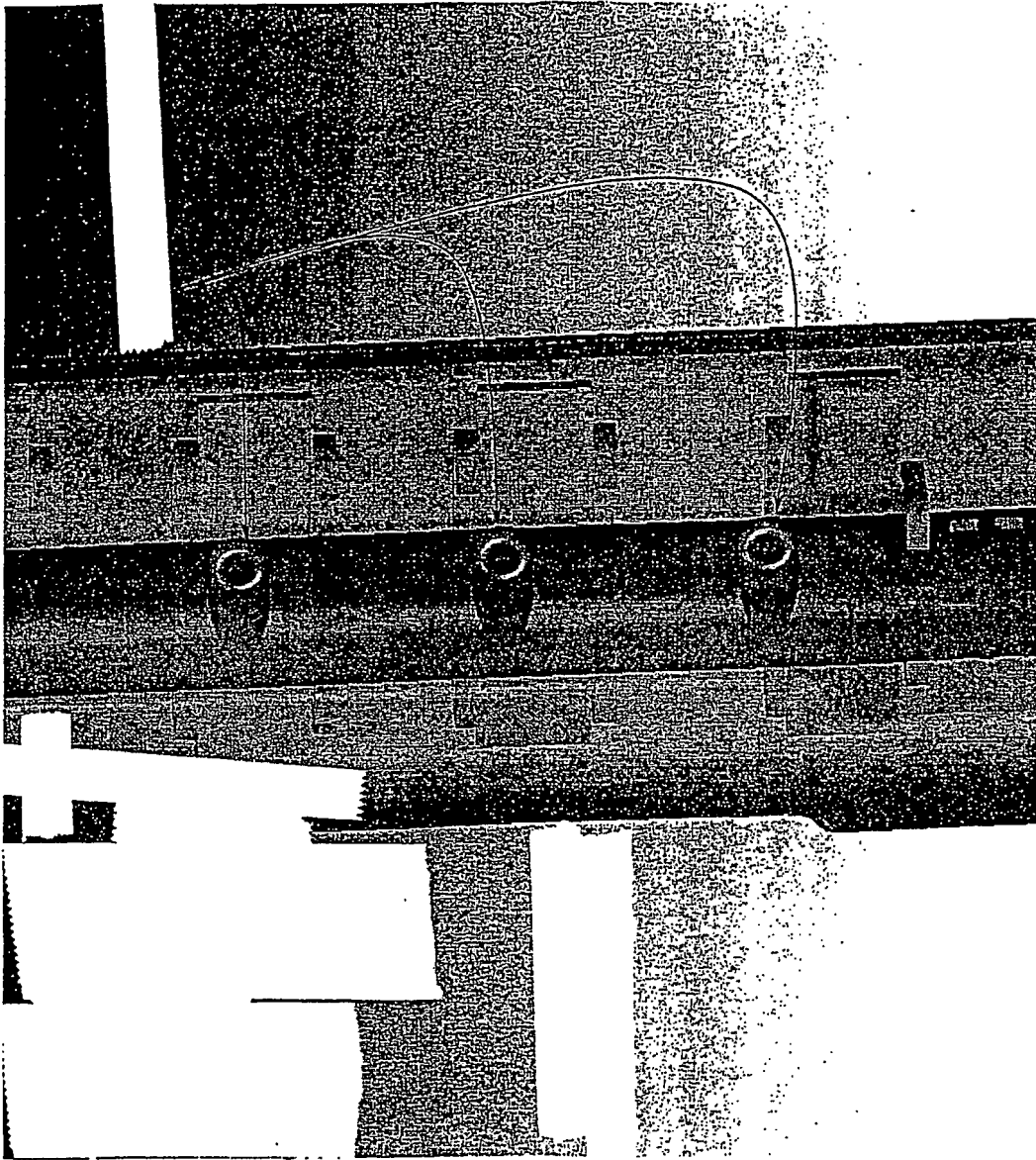


Fig. 138

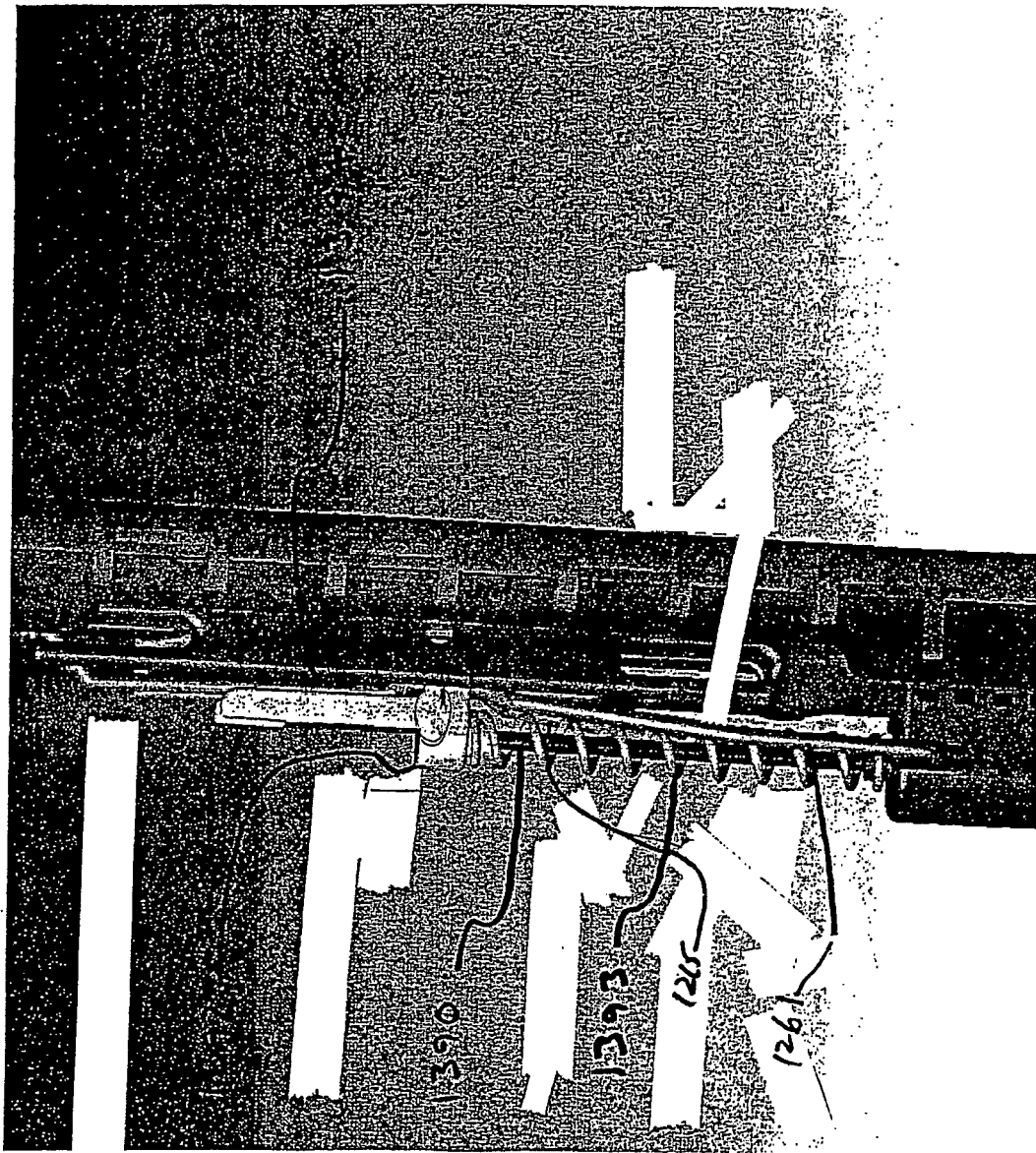
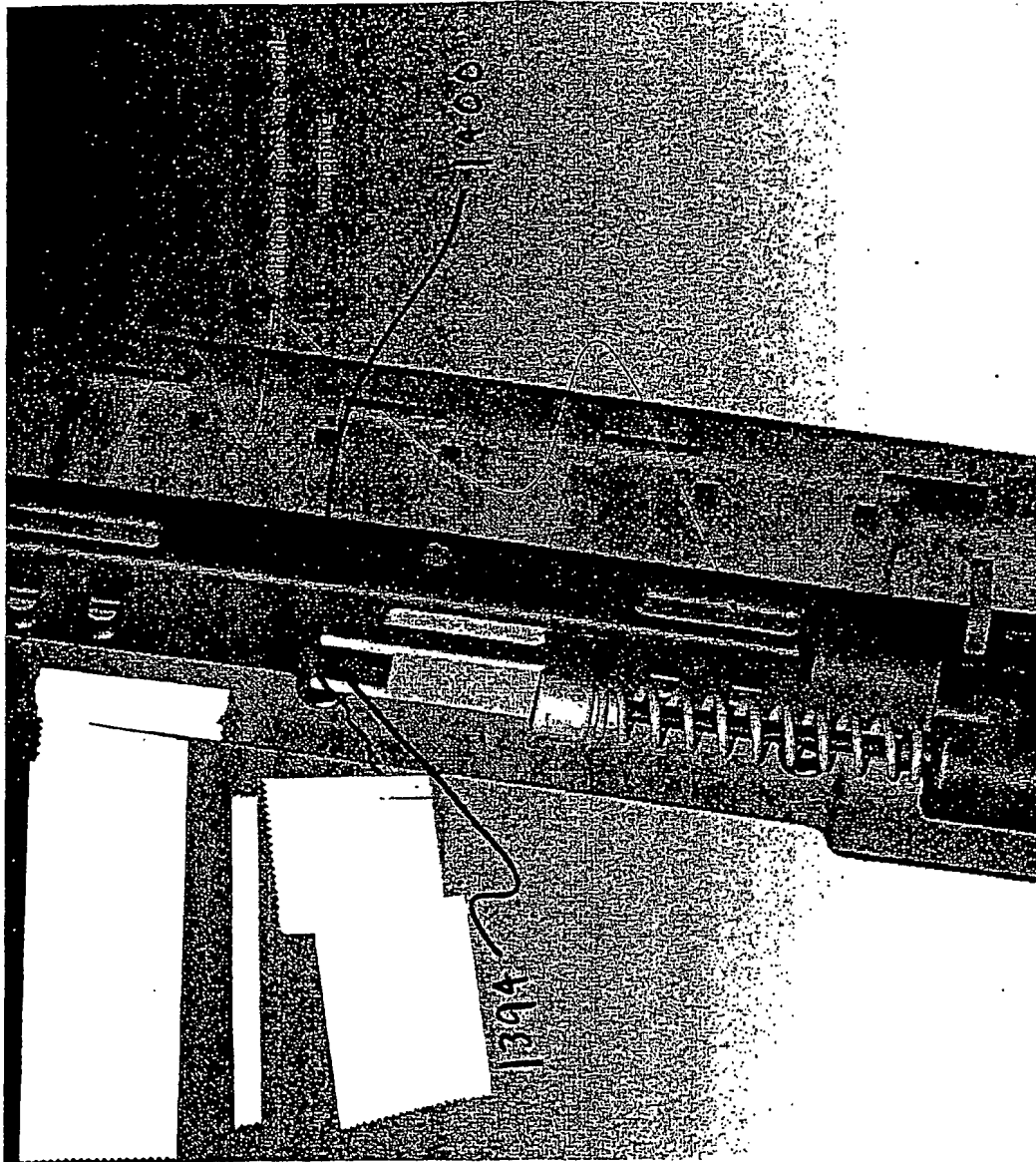


Fig. 139



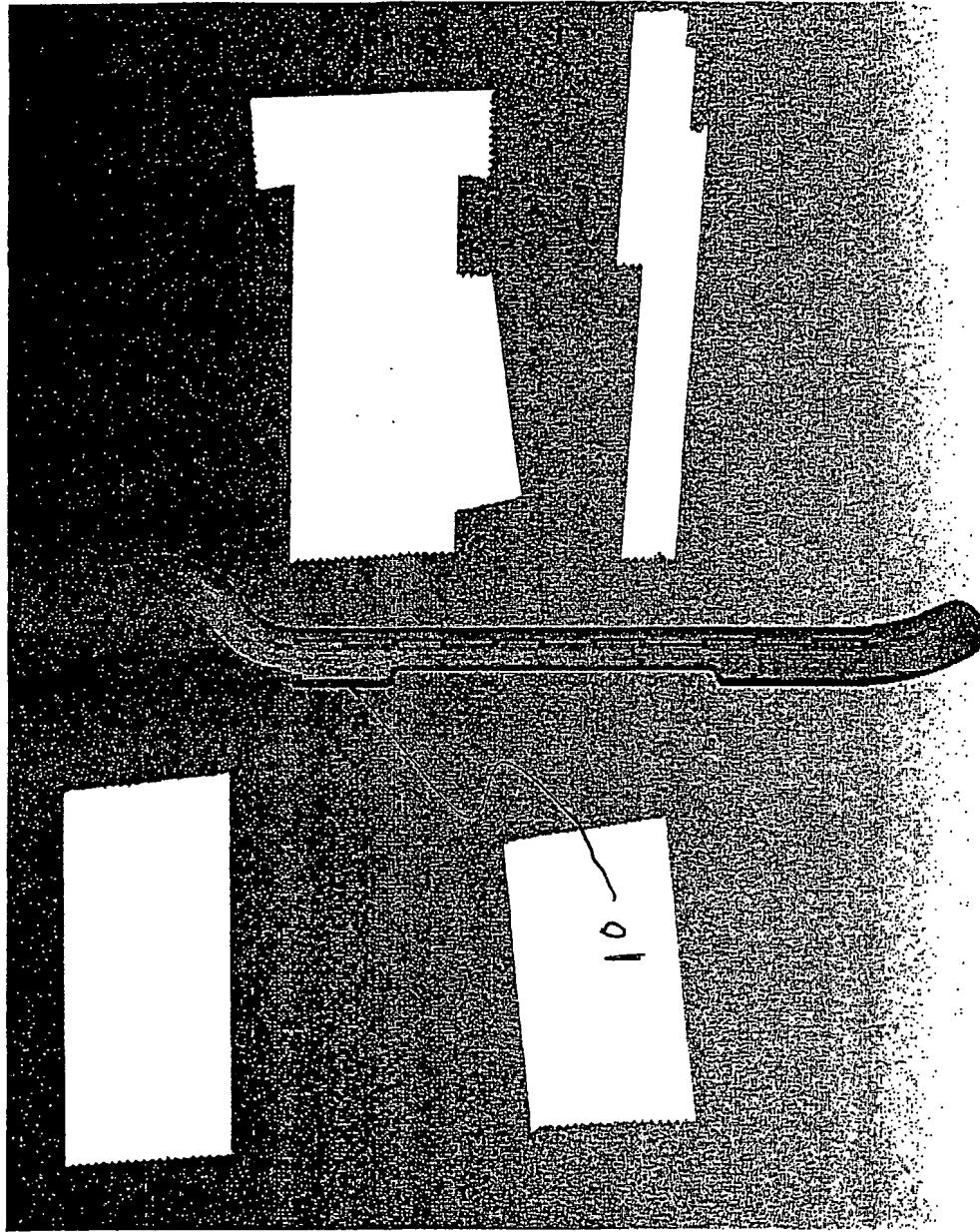


Fig. 141

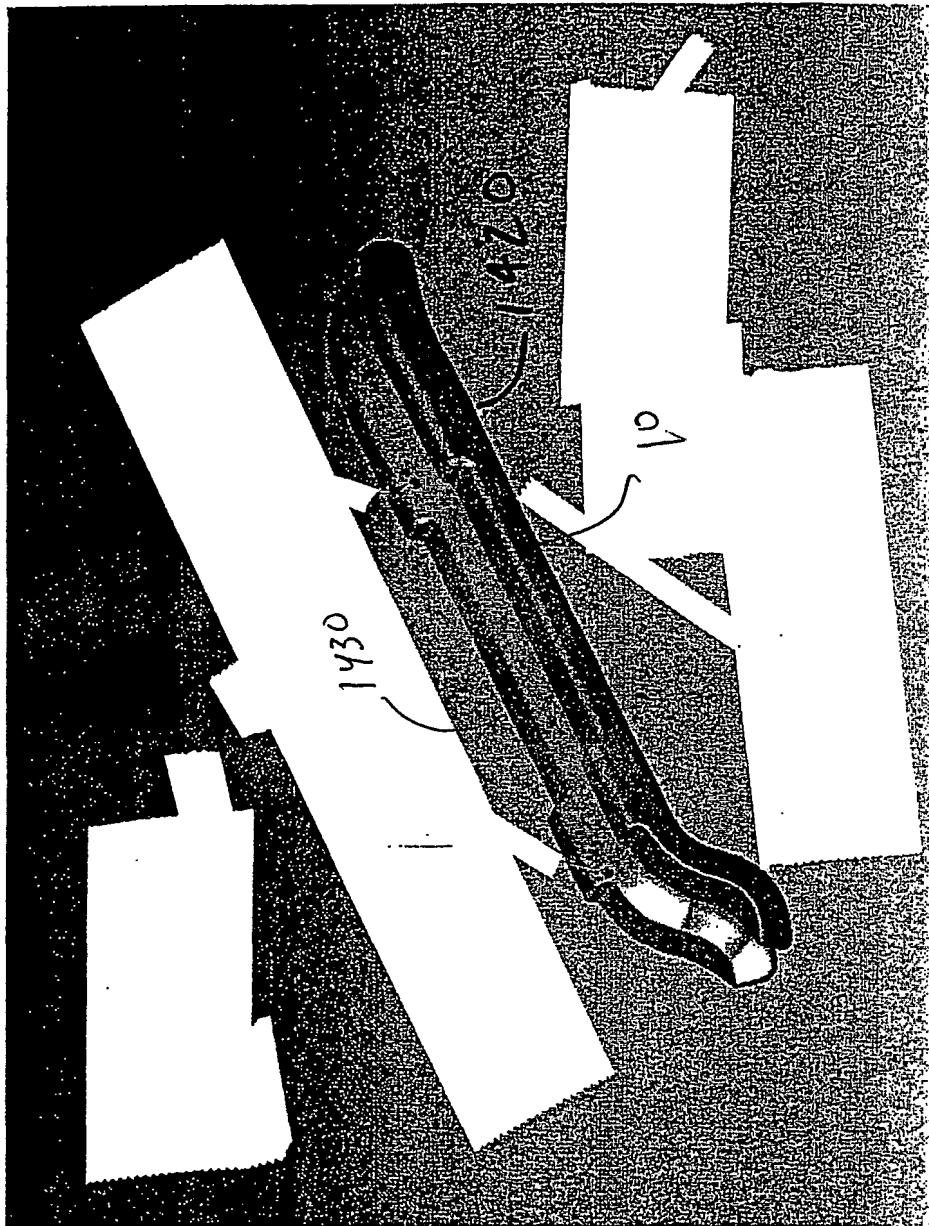


Fig. 142



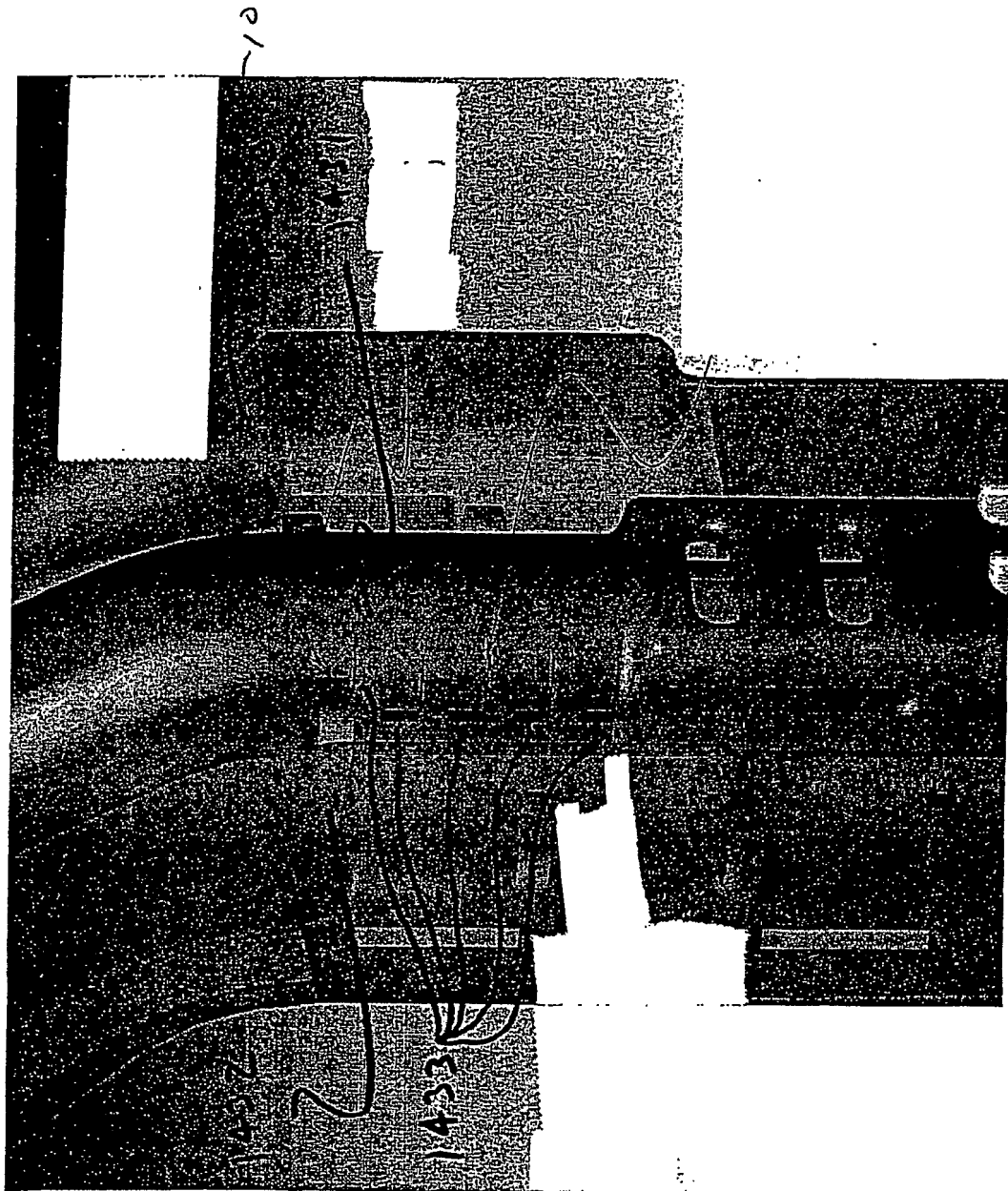


Fig. 143

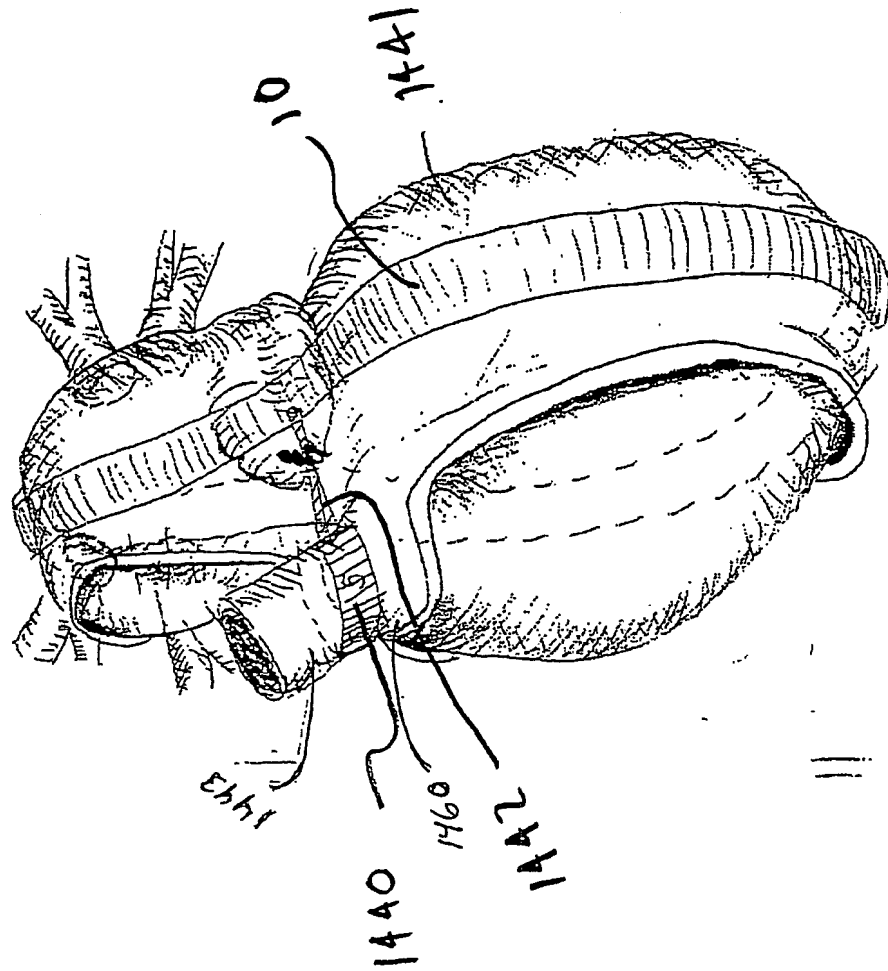
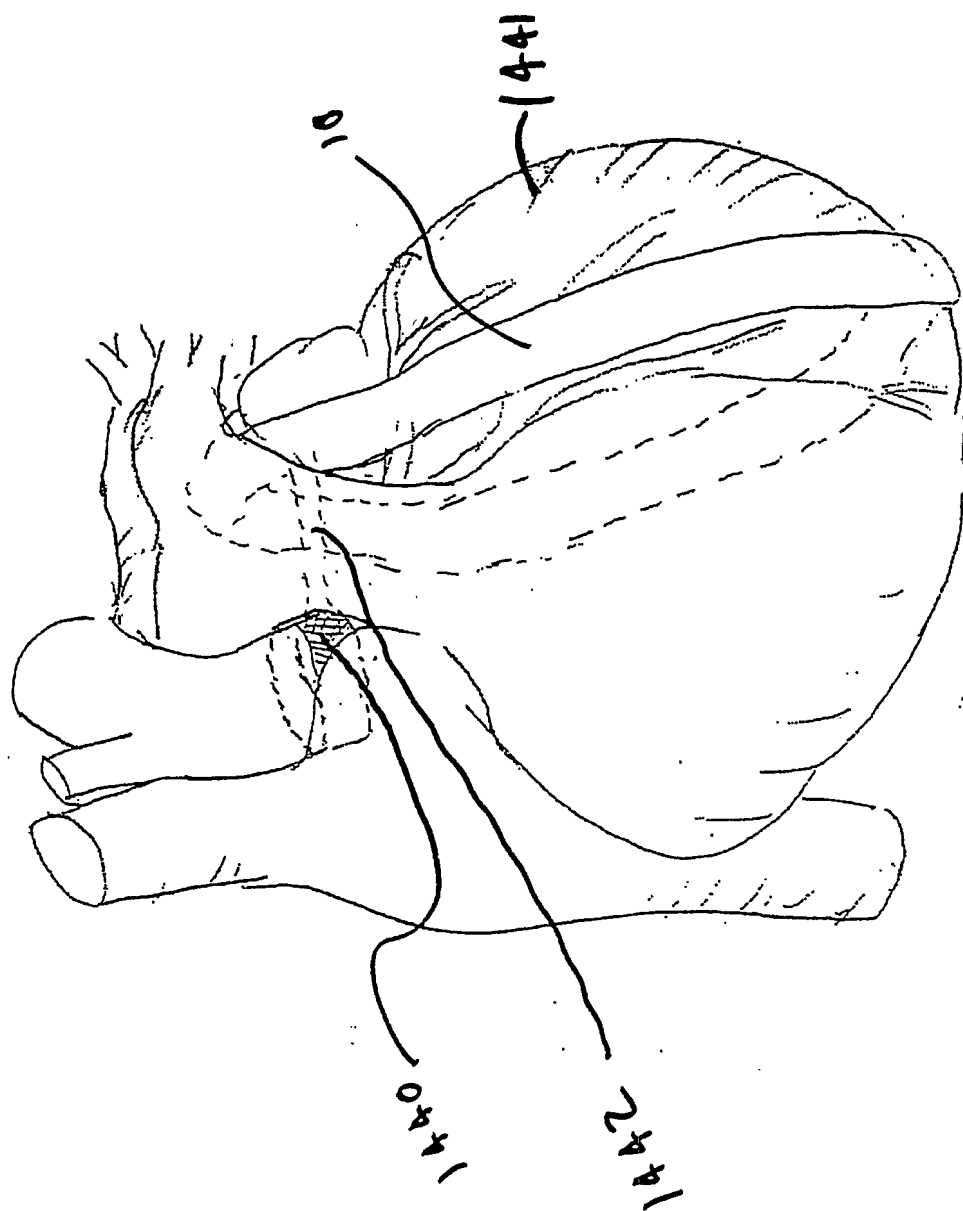
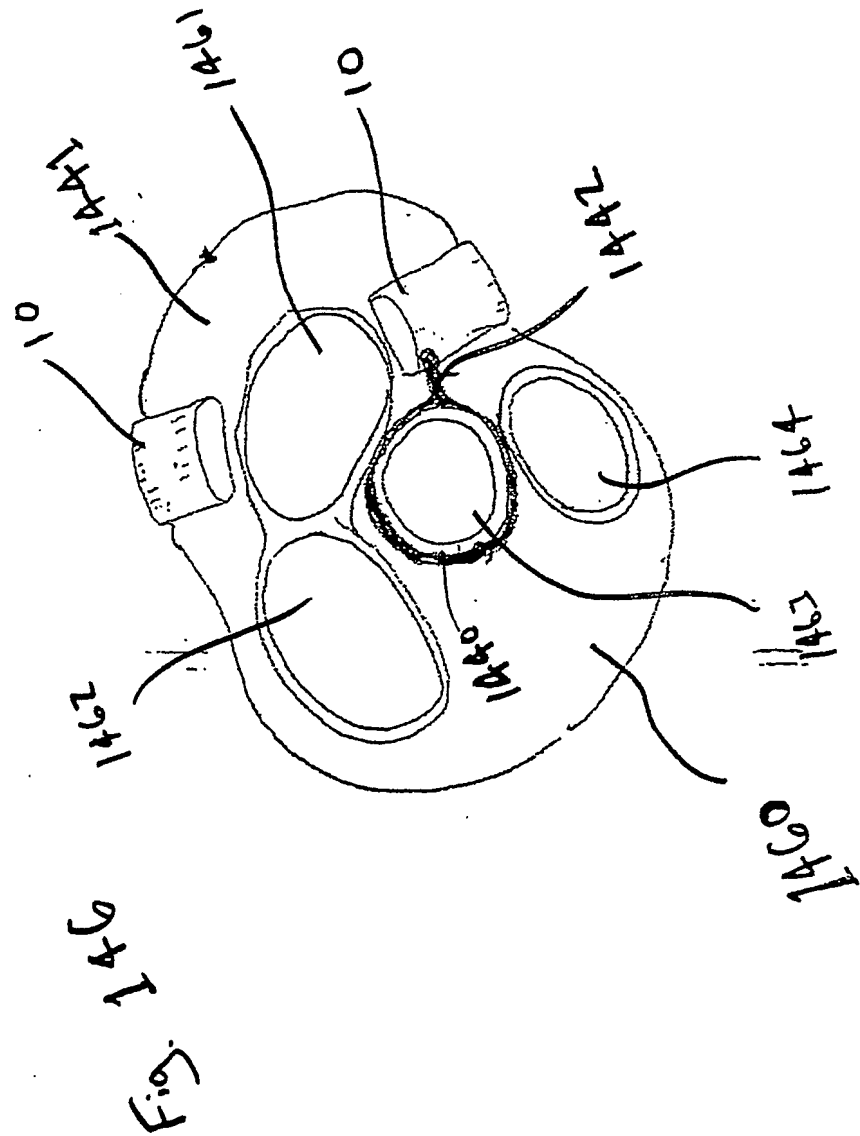


Fig. 144





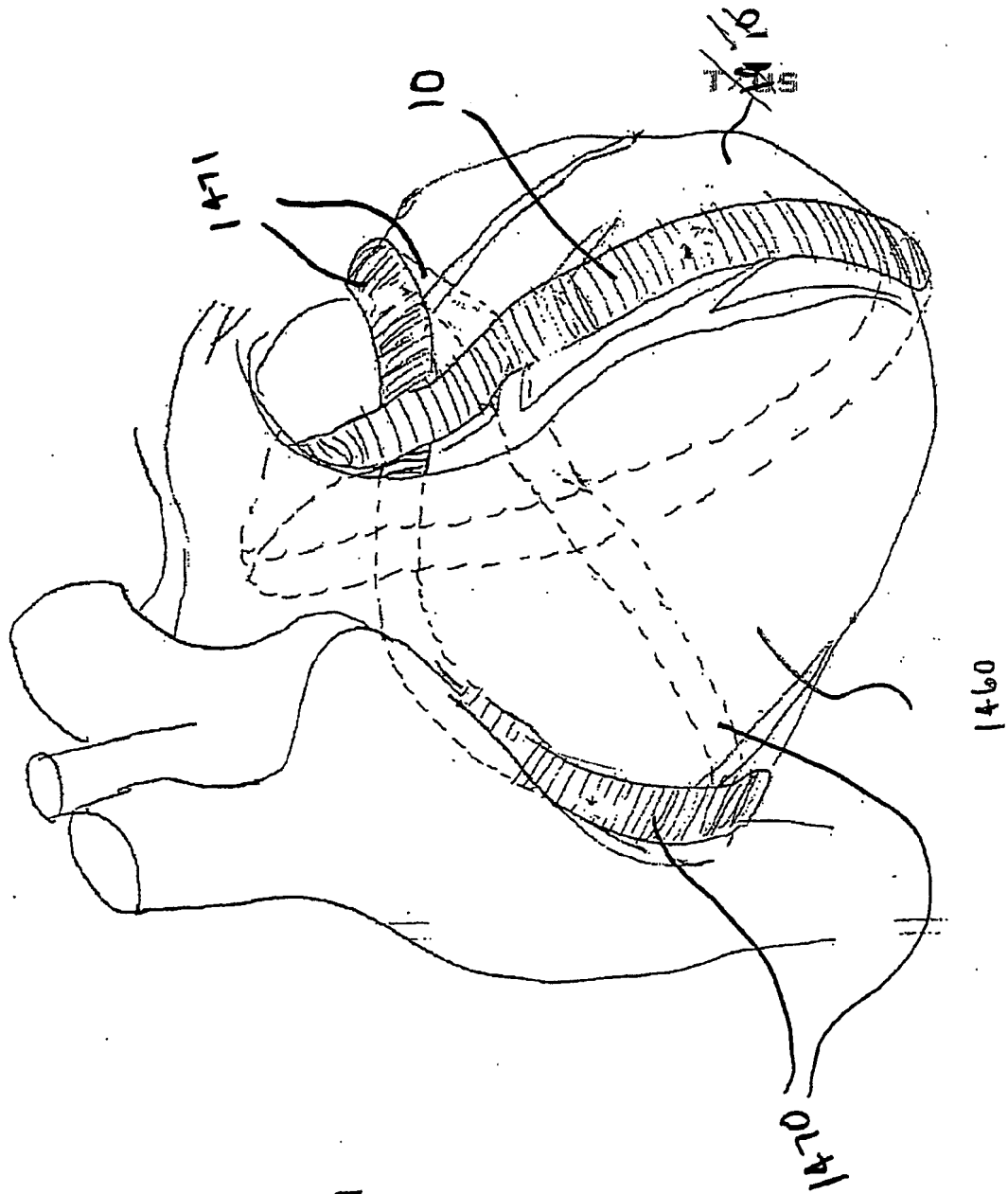


Fig. 147

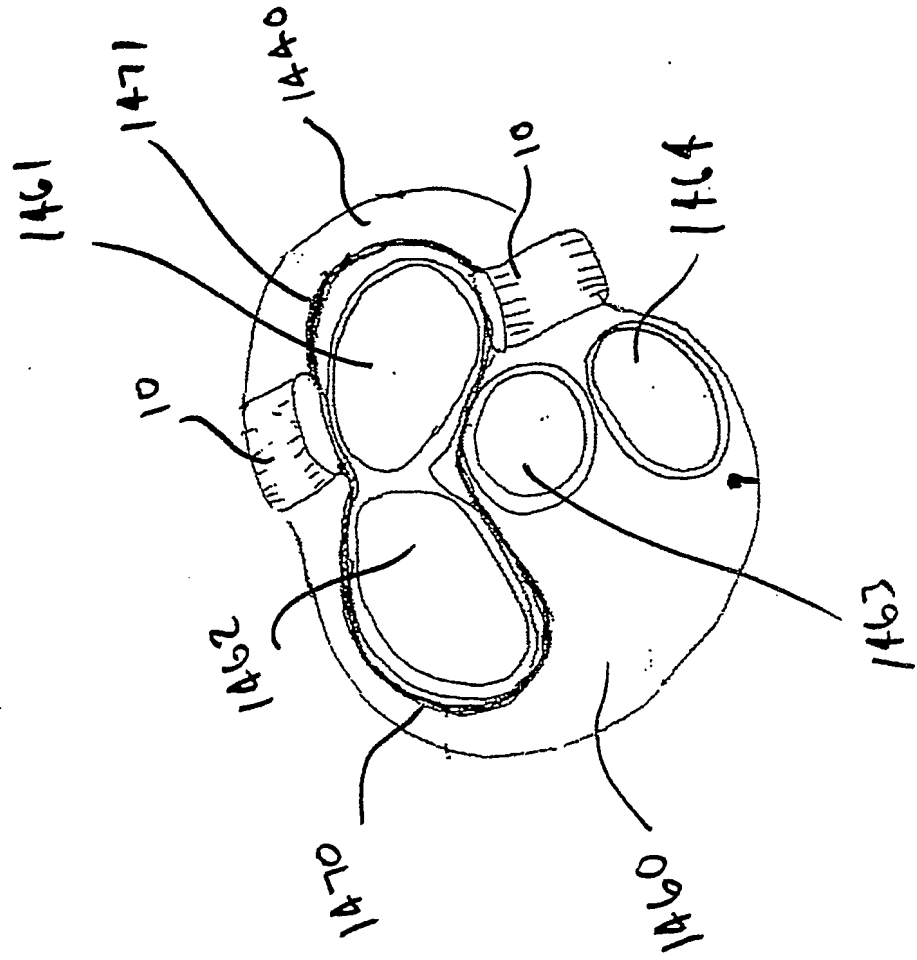


Fig 148

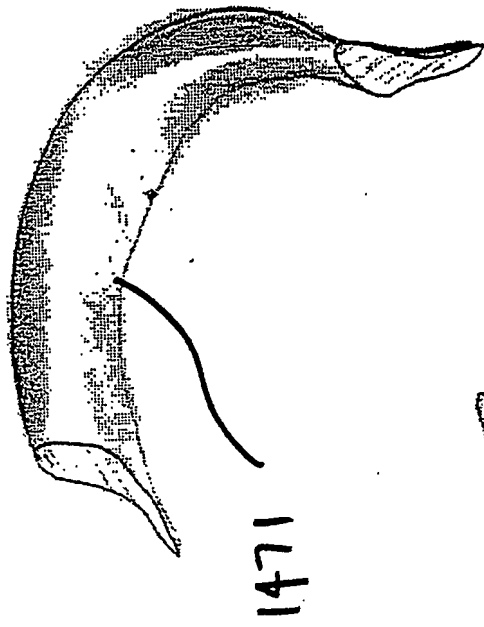


Fig. 1471a

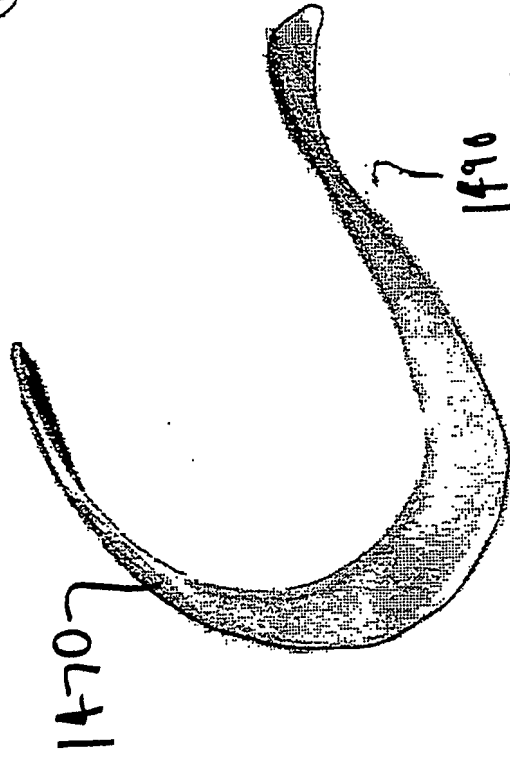
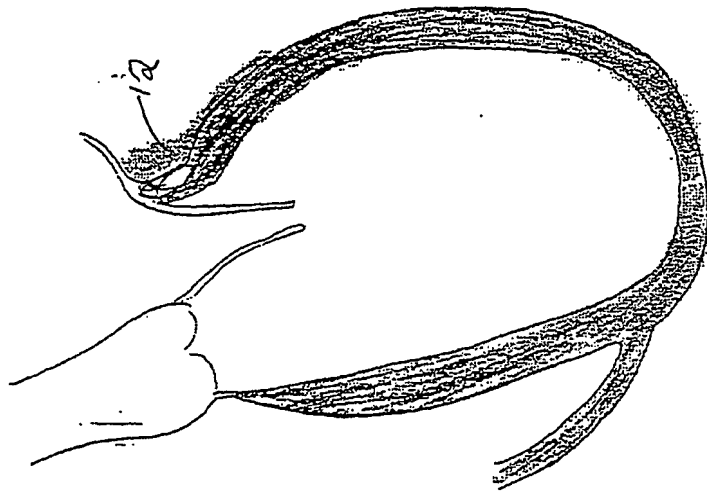


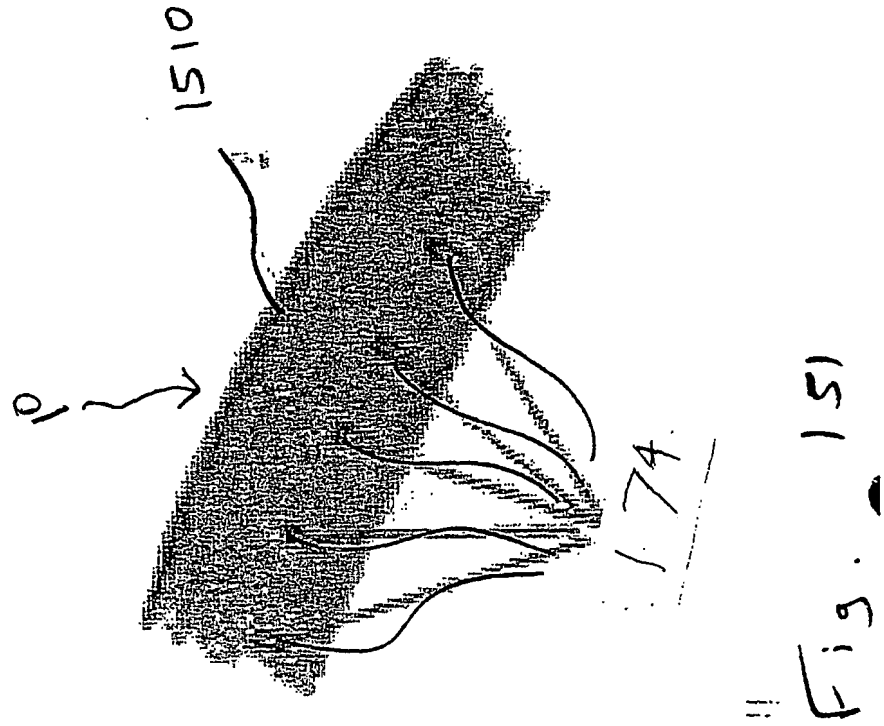
Fig. 1470b



150

Fig.





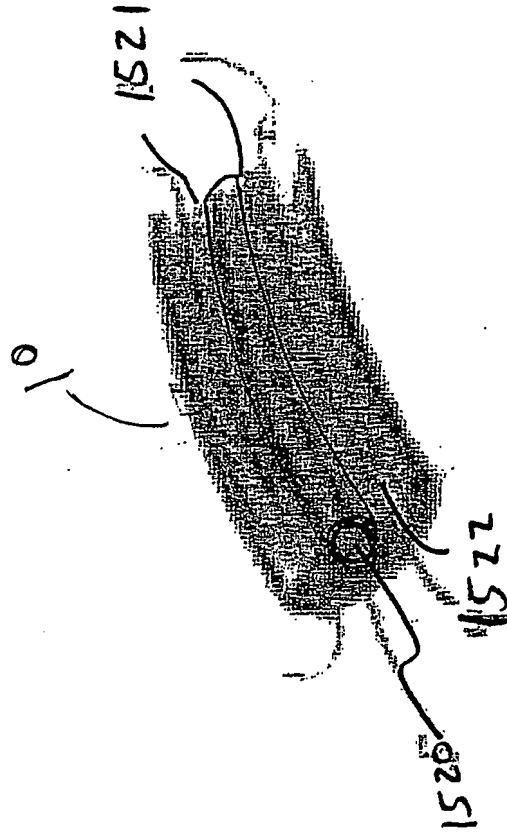
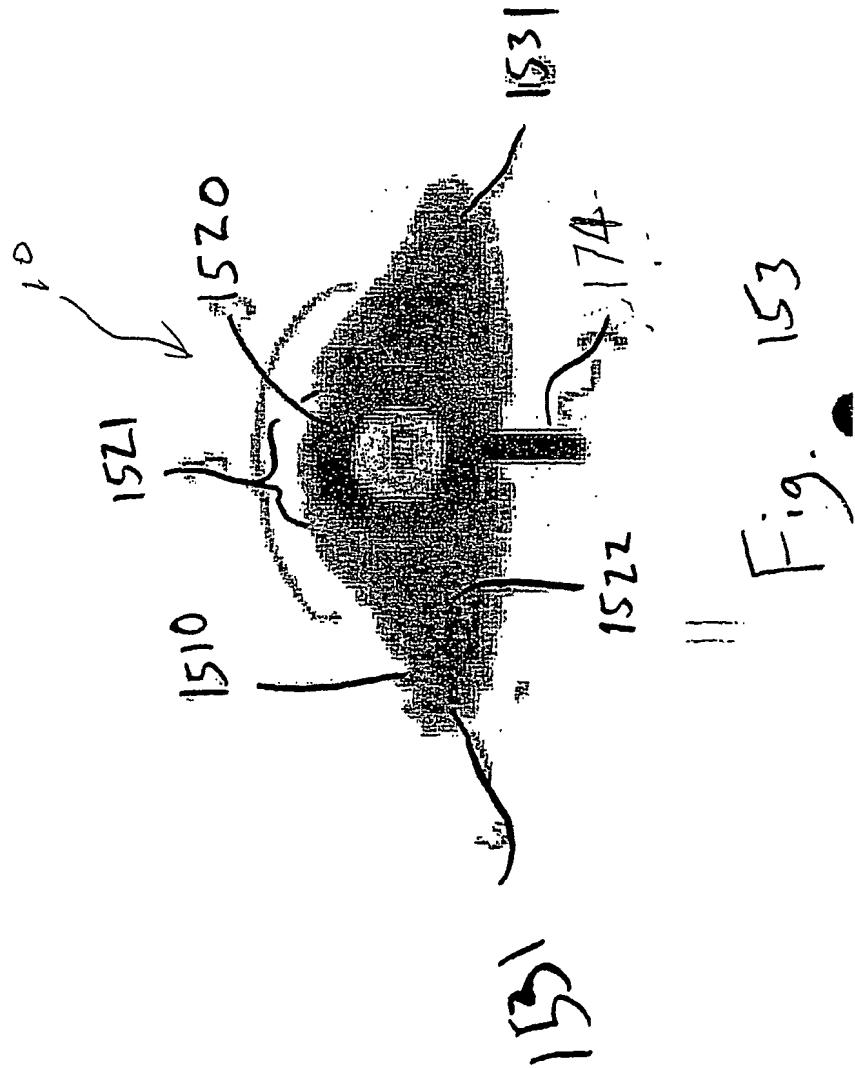


Fig. 152



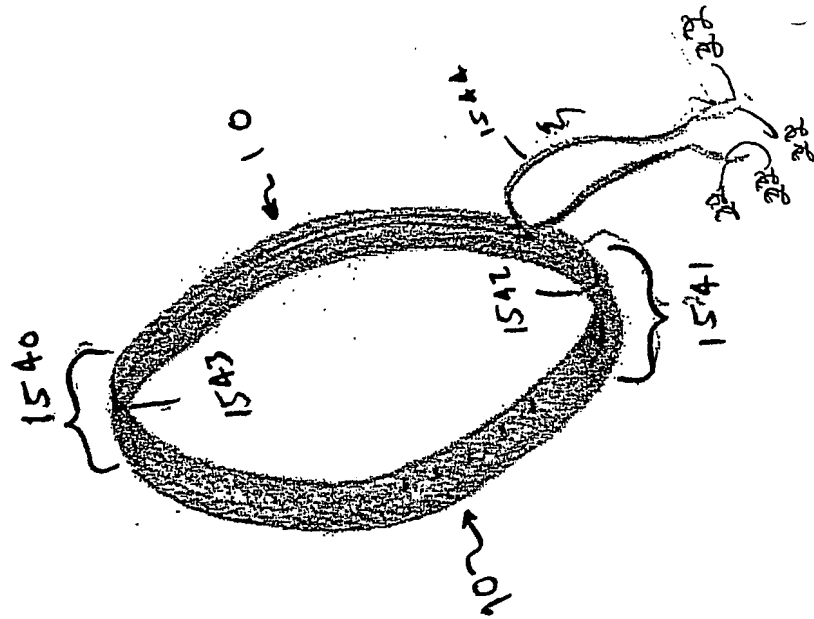


Fig. 154

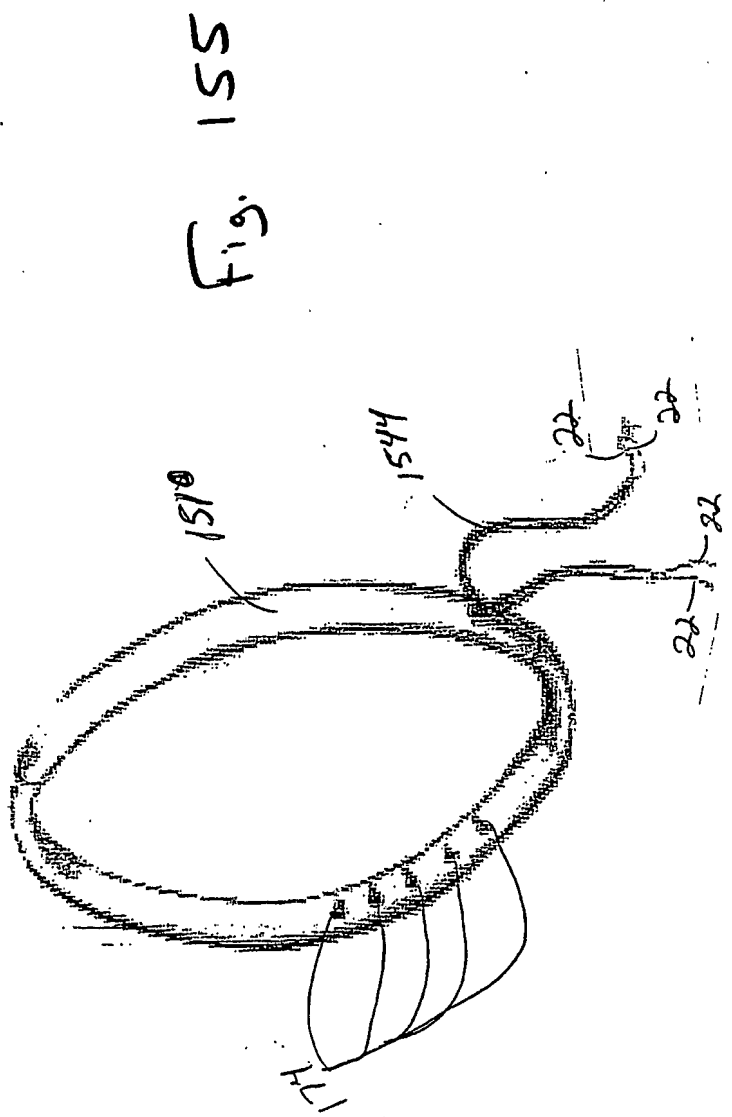


Fig. 156

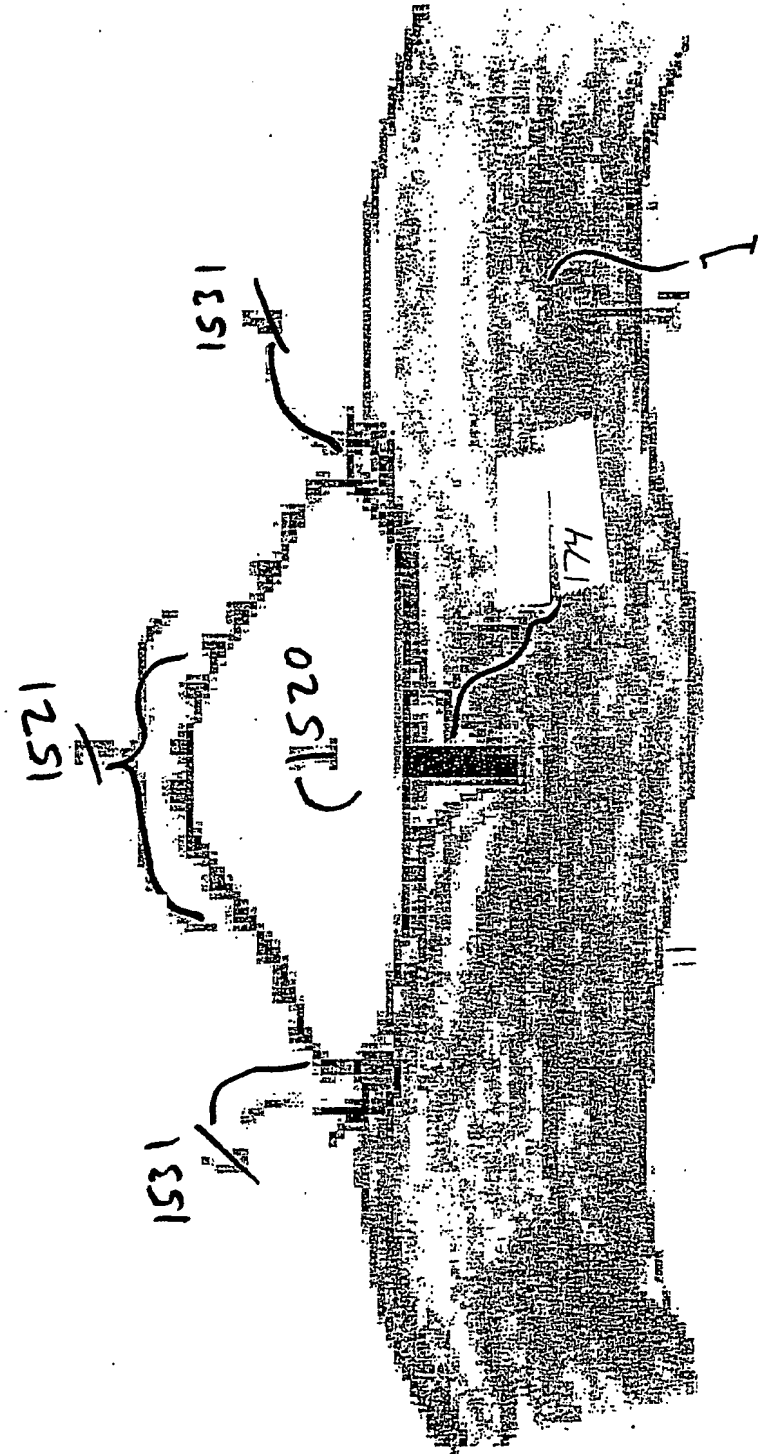


Fig. 157

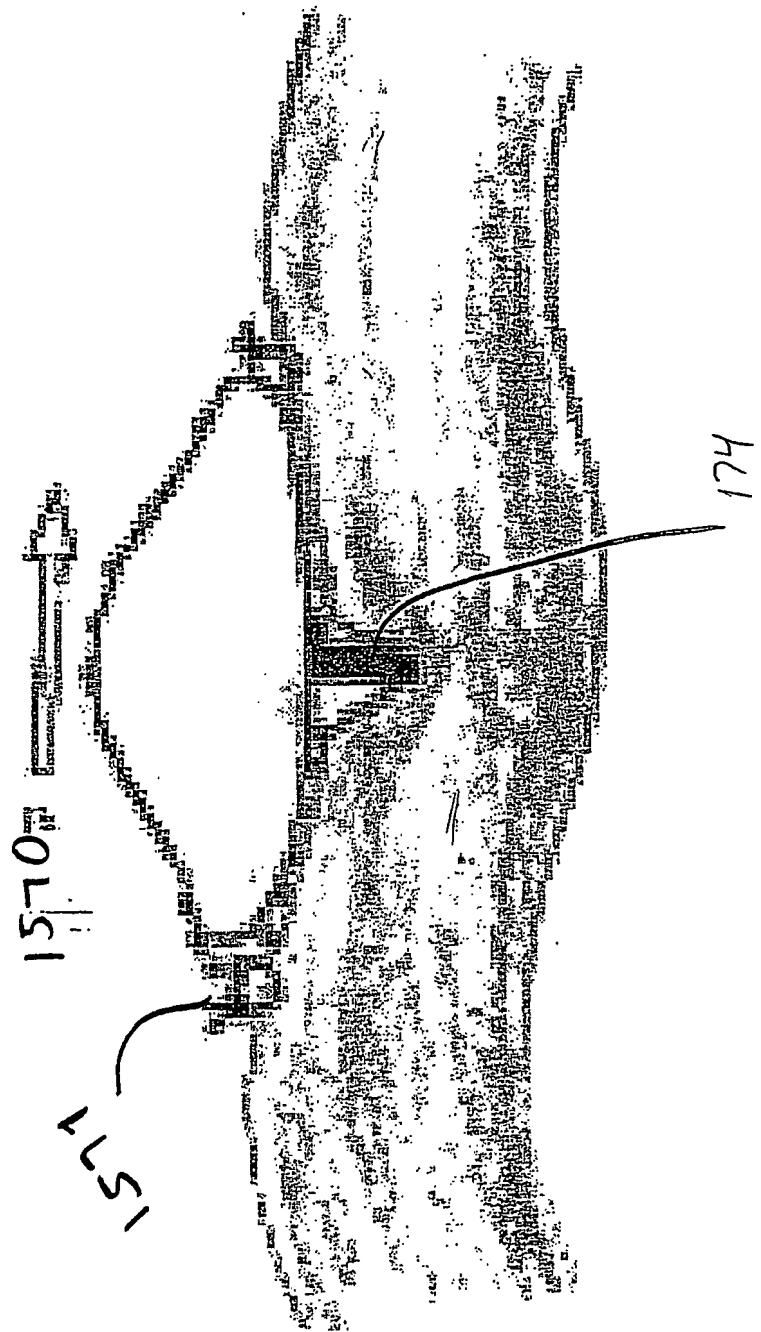
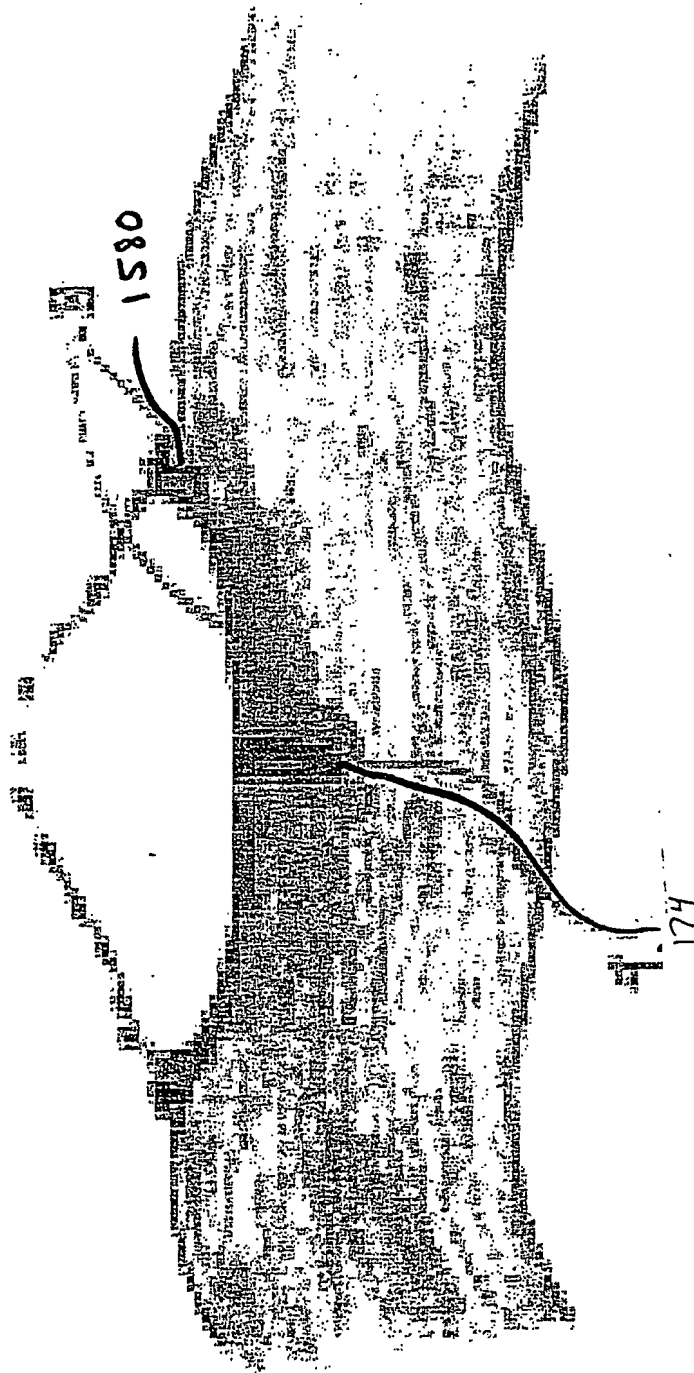


Fig. 158





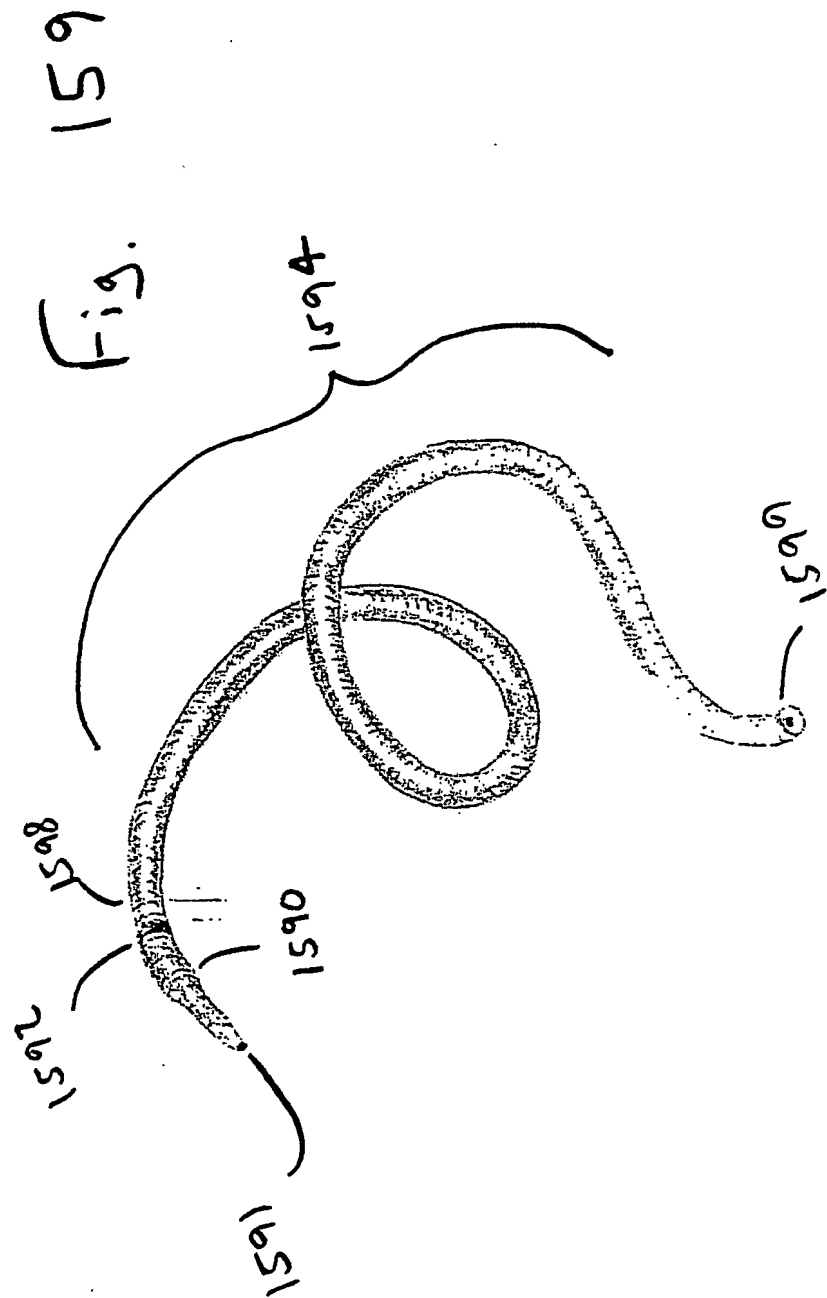


Fig. 160

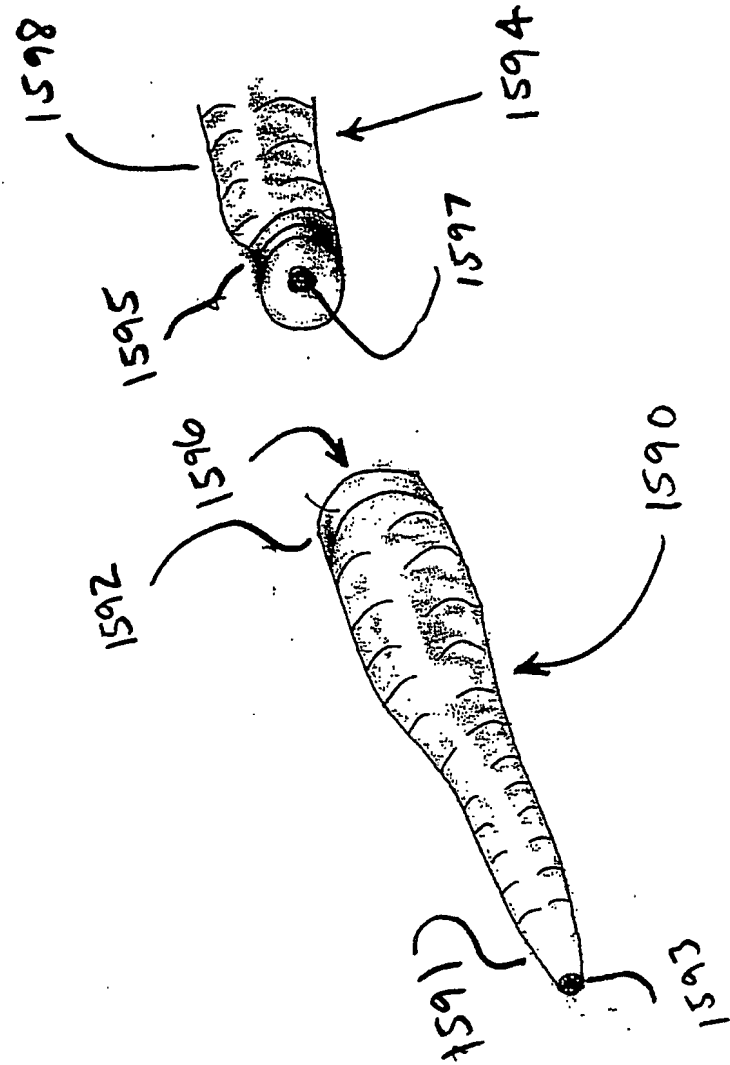
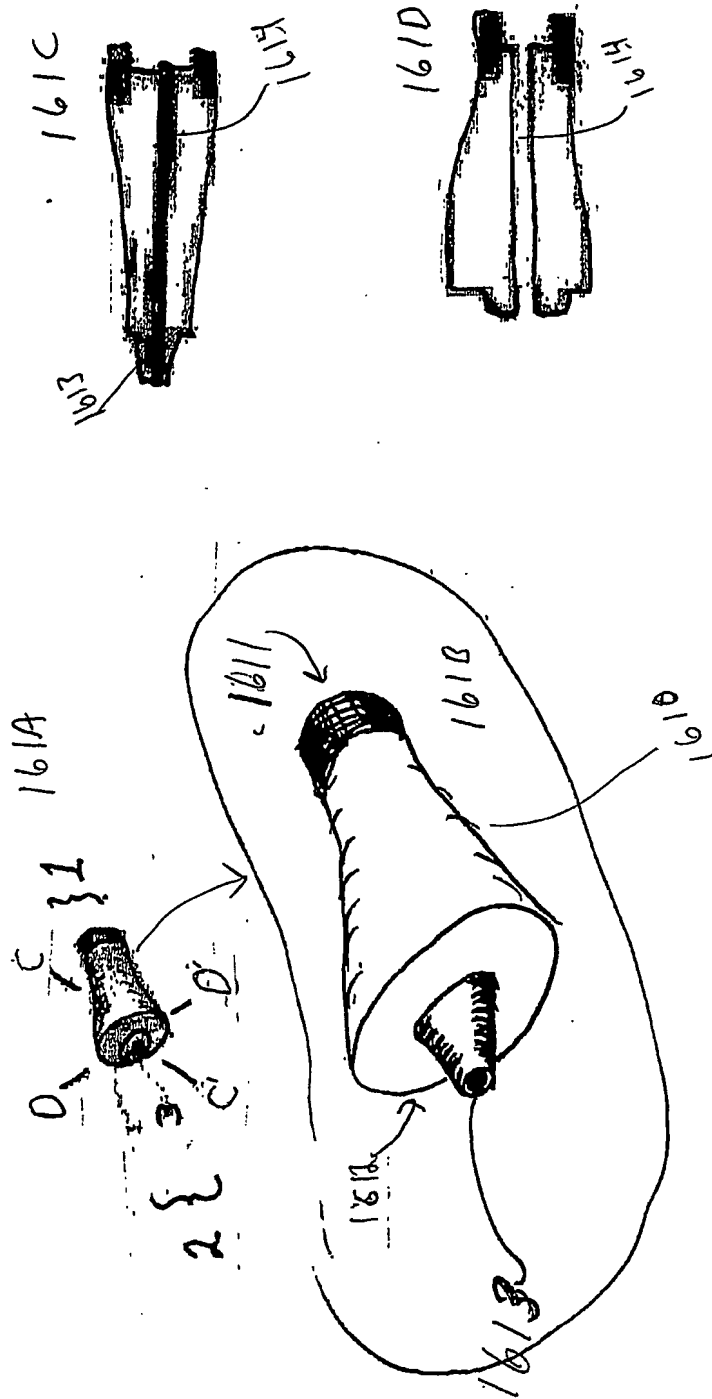


Fig. 161



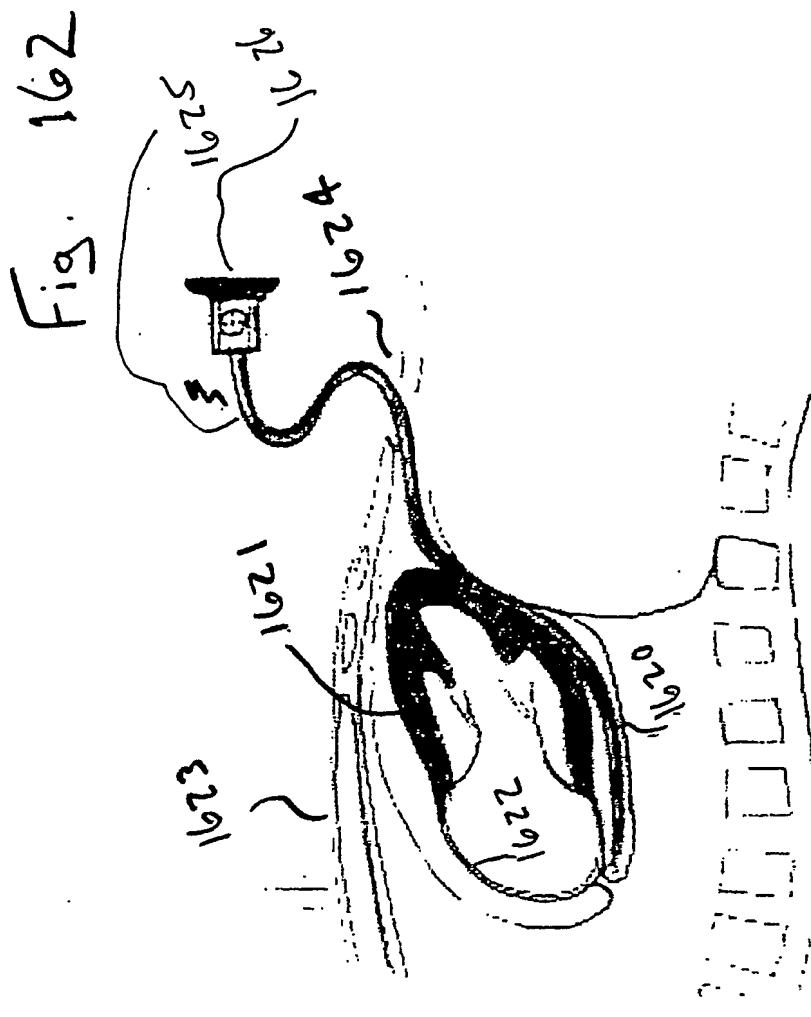


Fig. 163

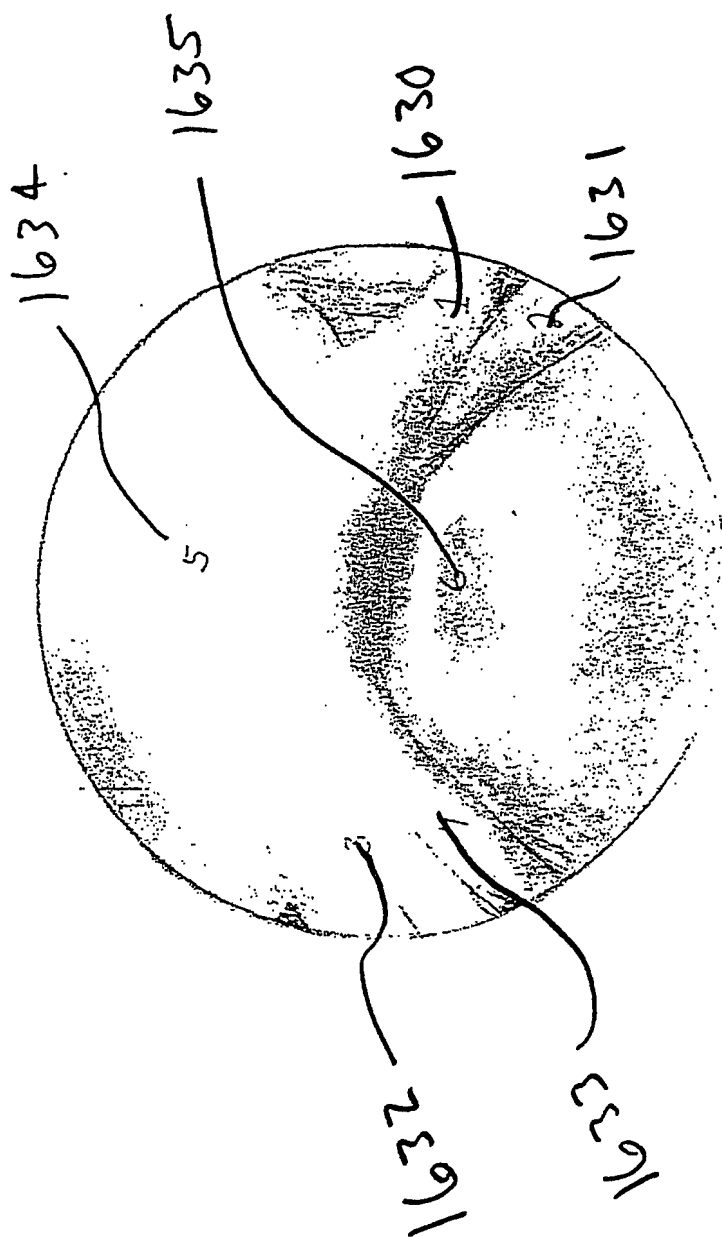


Fig. 164

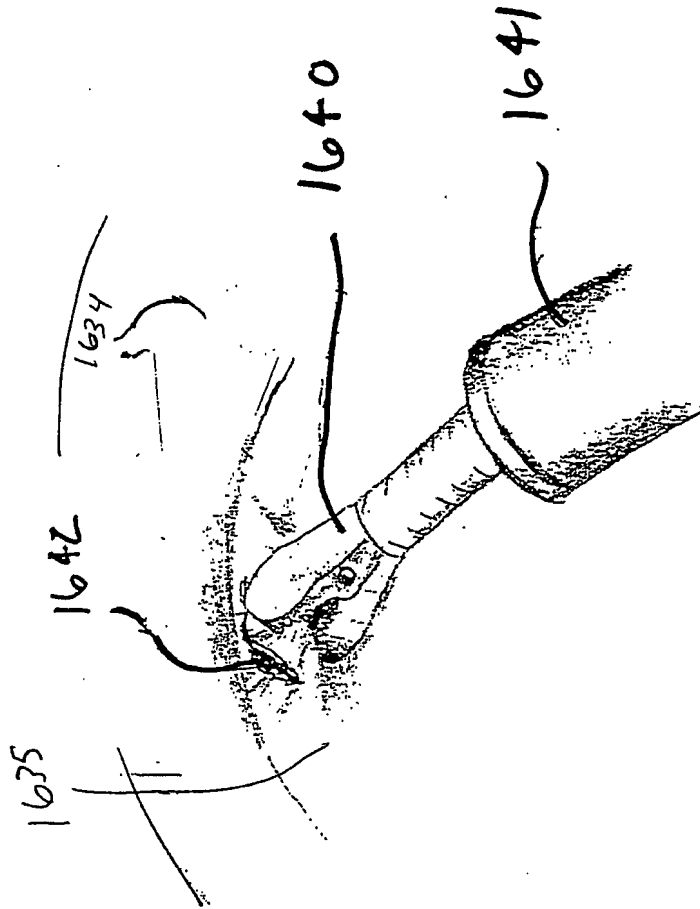


Fig. 165

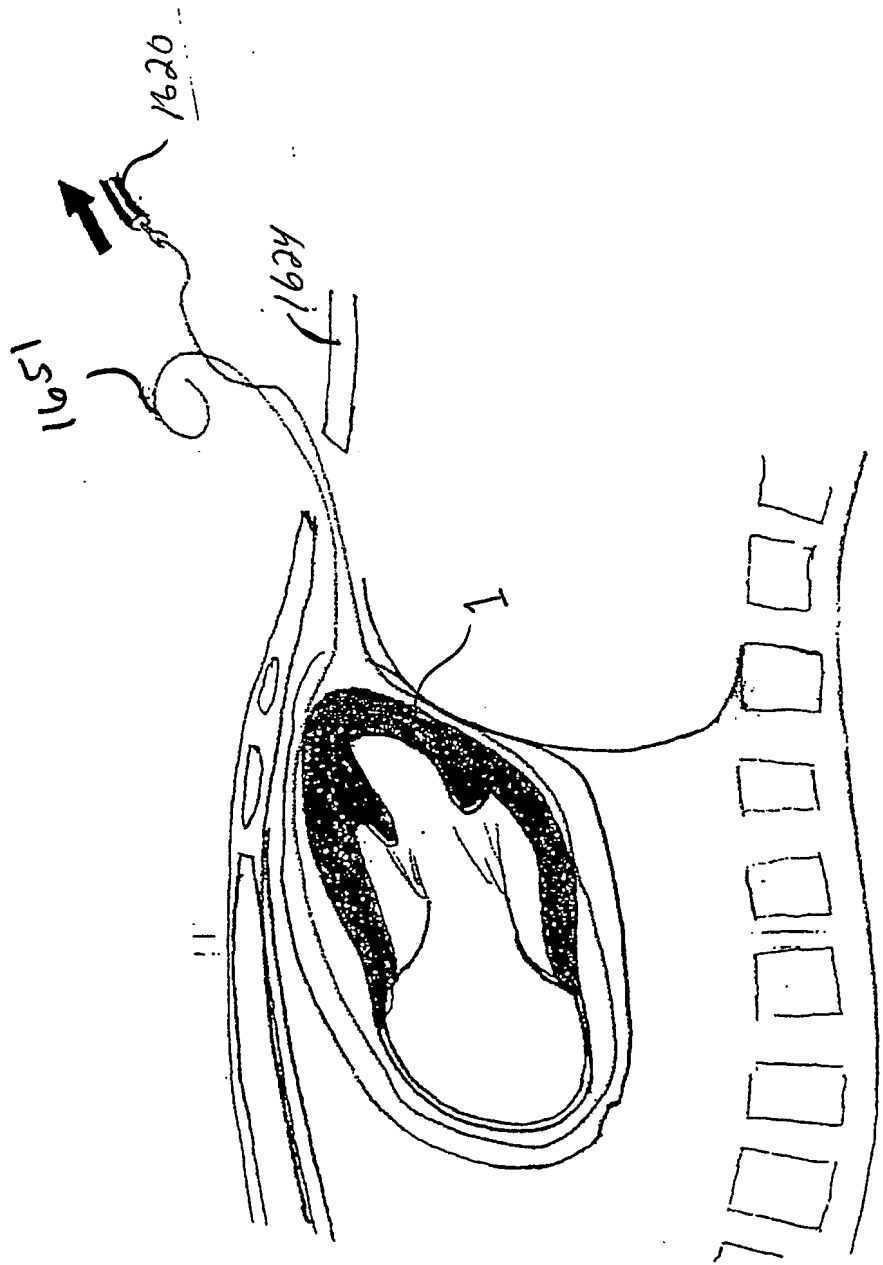


Fig. 166

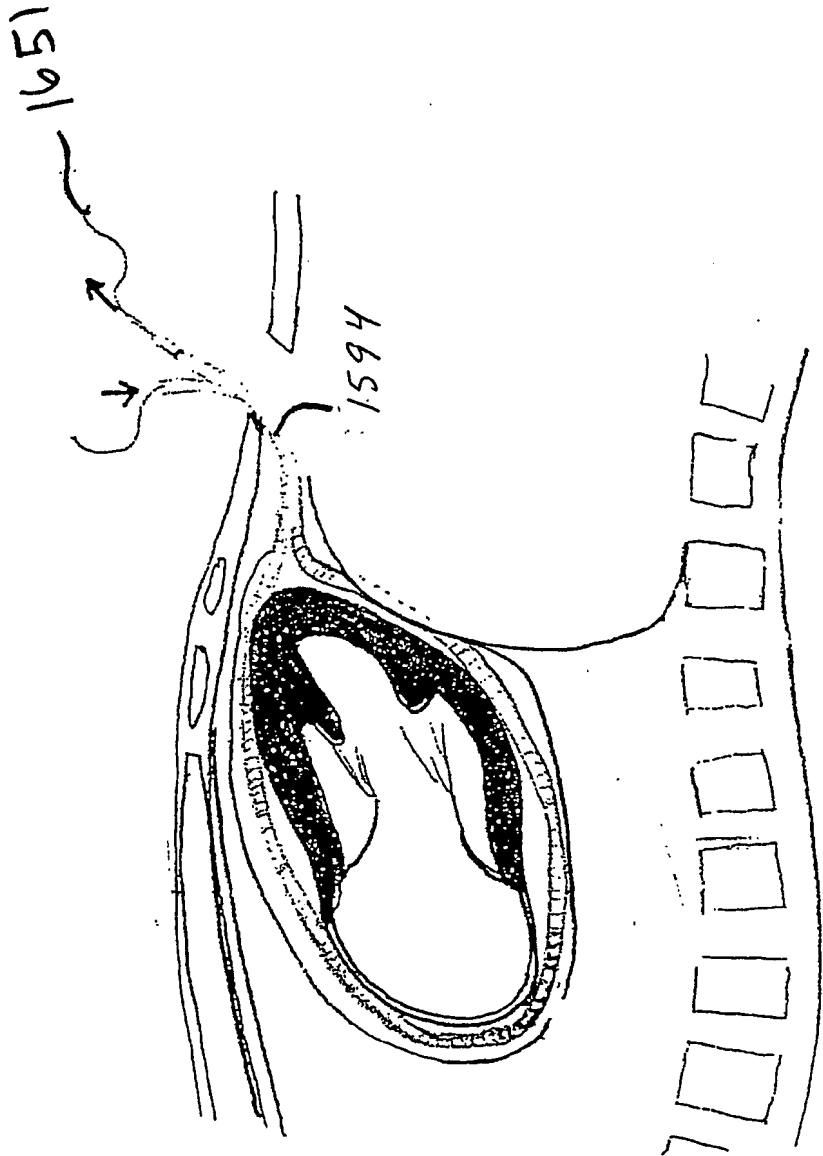




Fig. 167

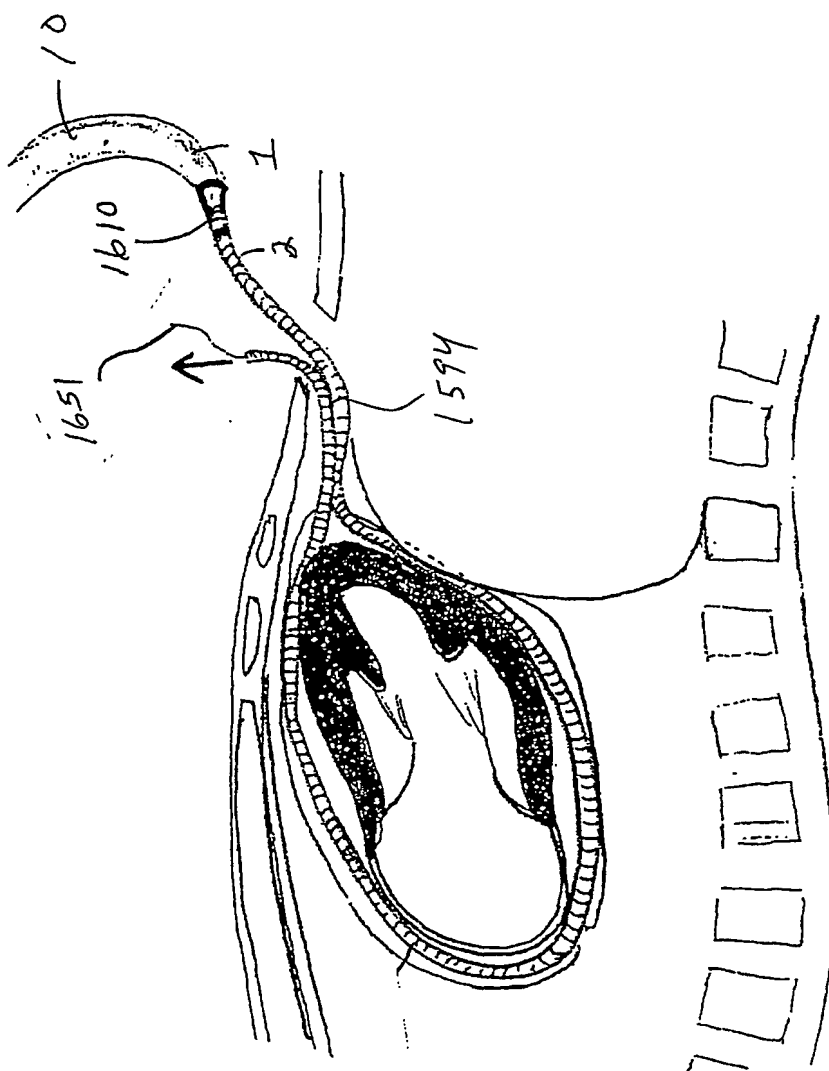
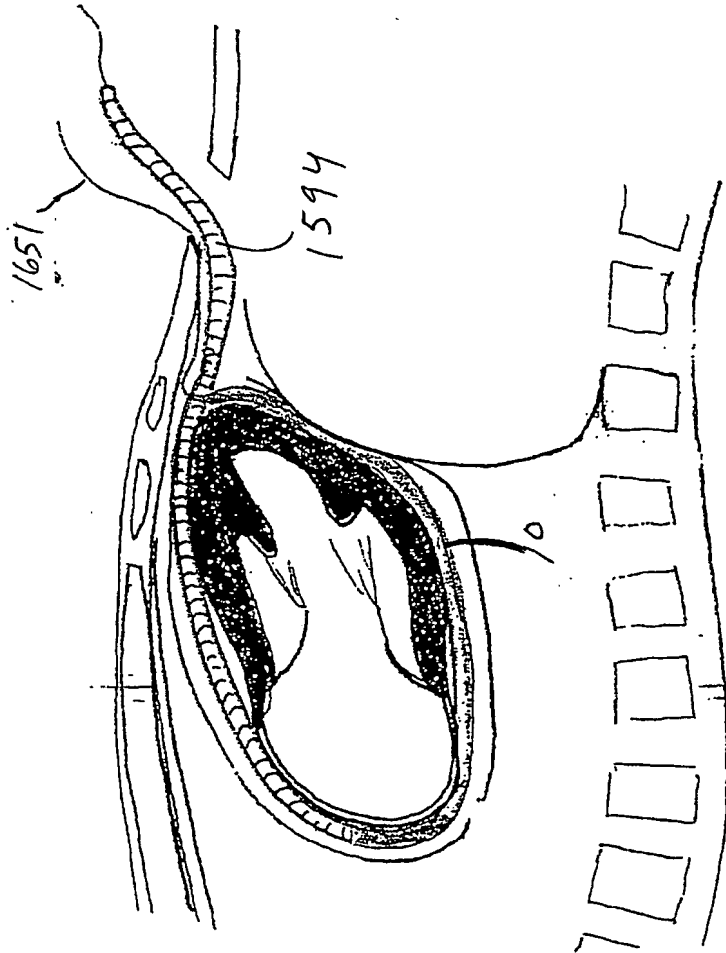
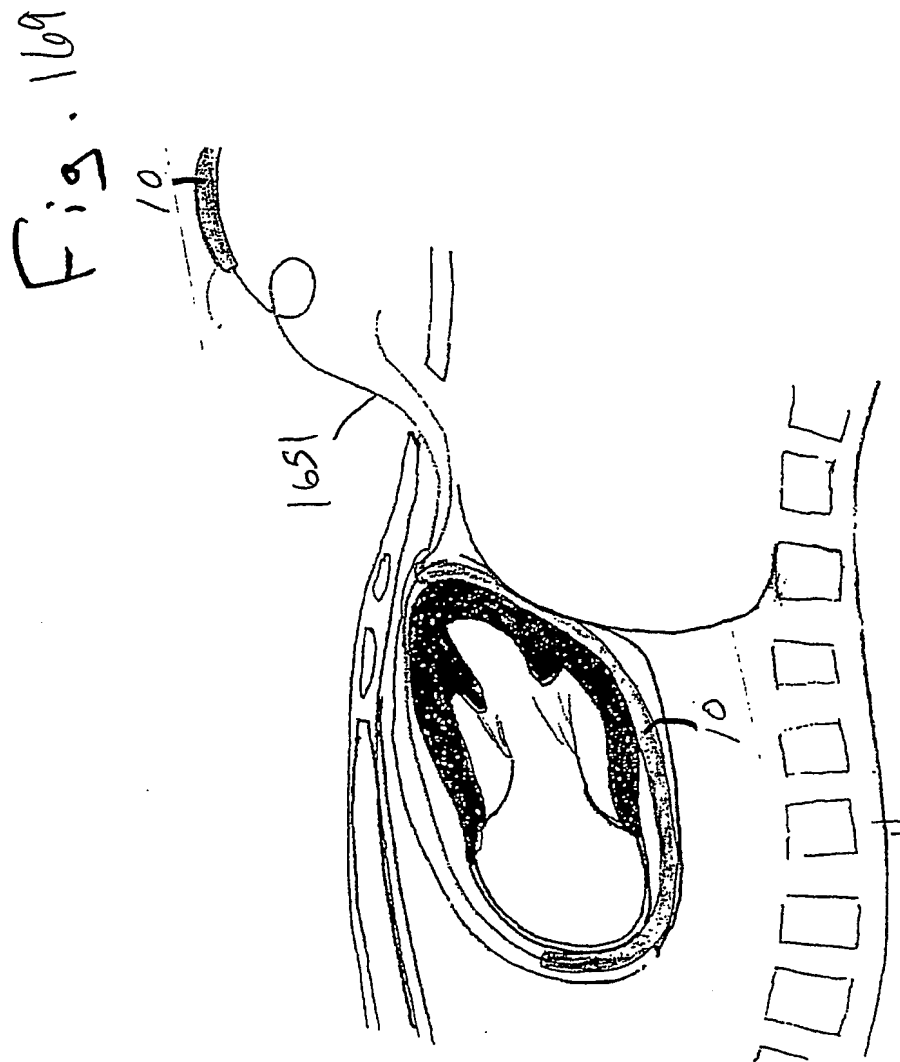


Fig. 168





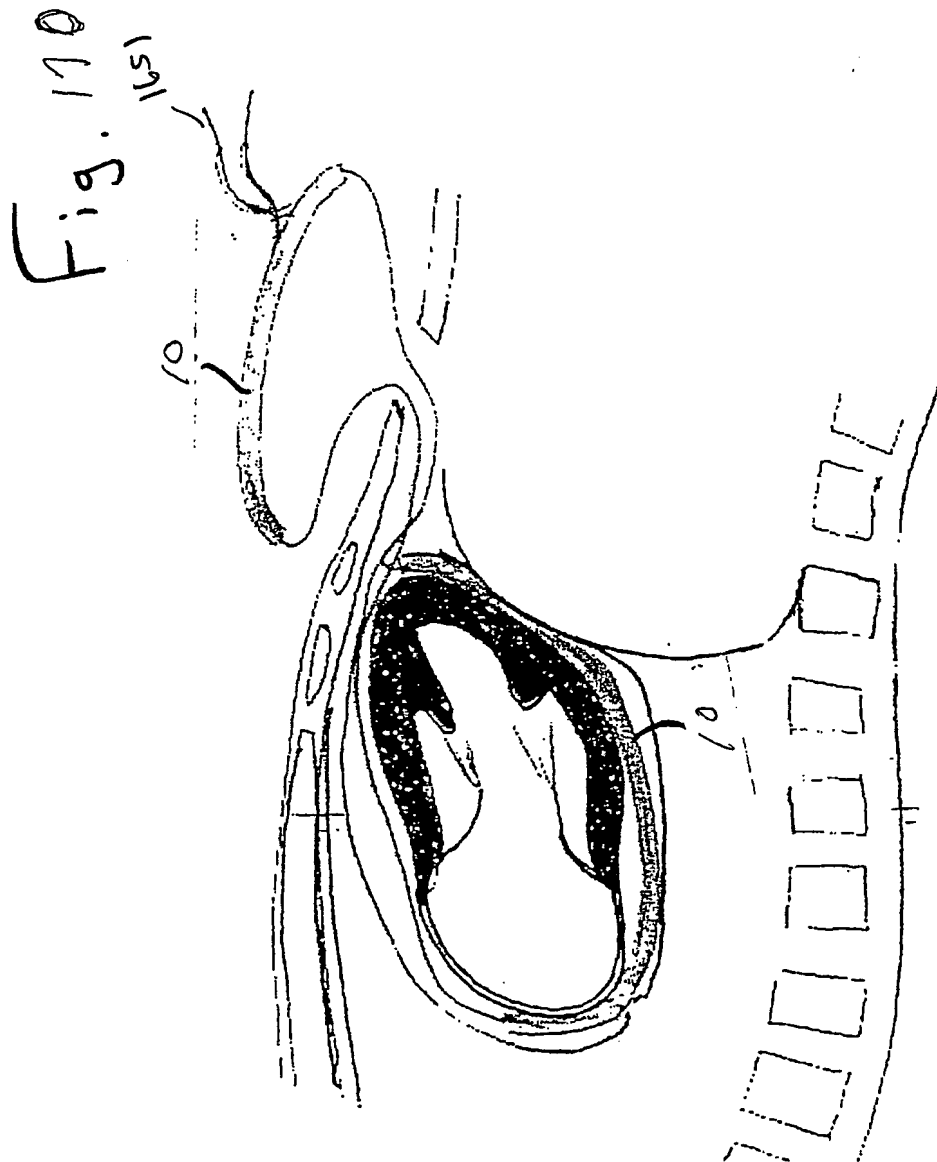
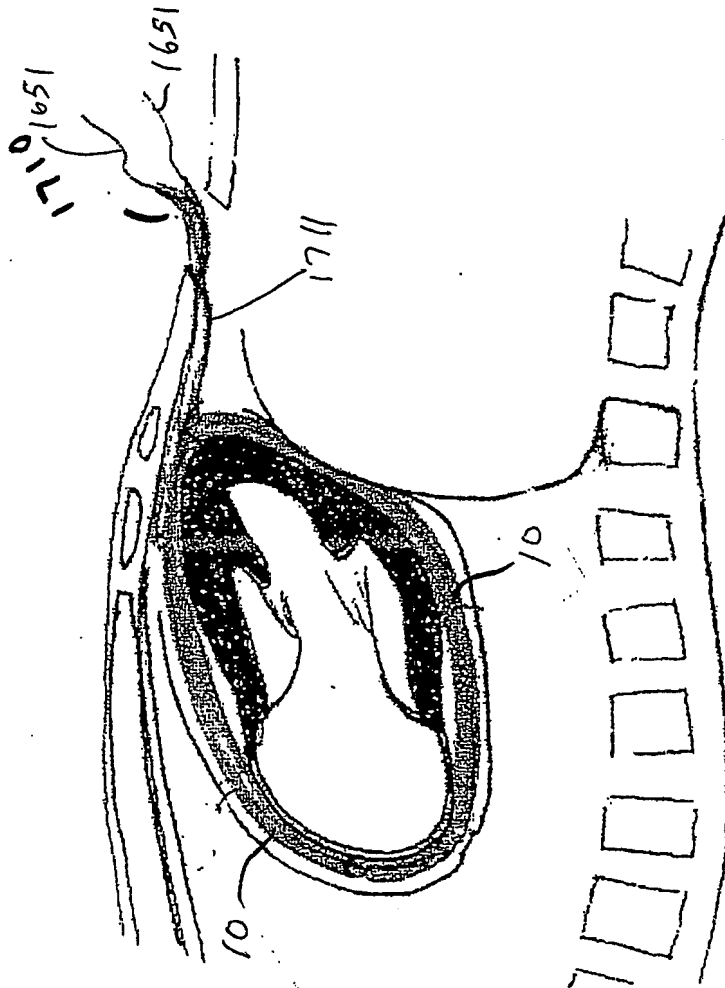
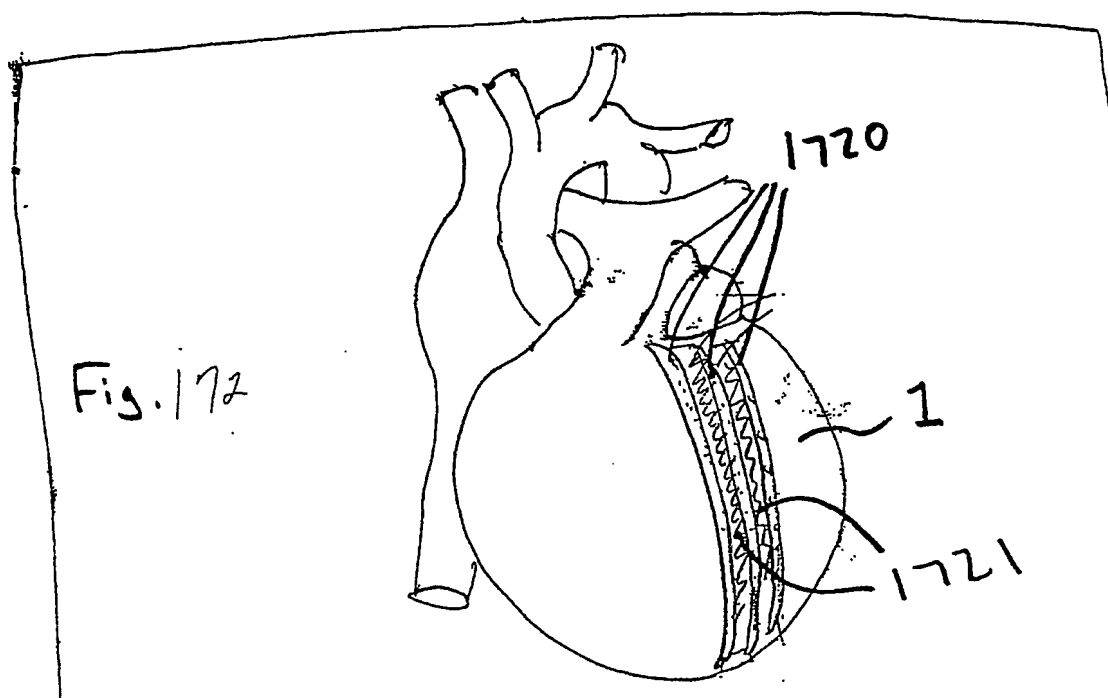


Fig. 171





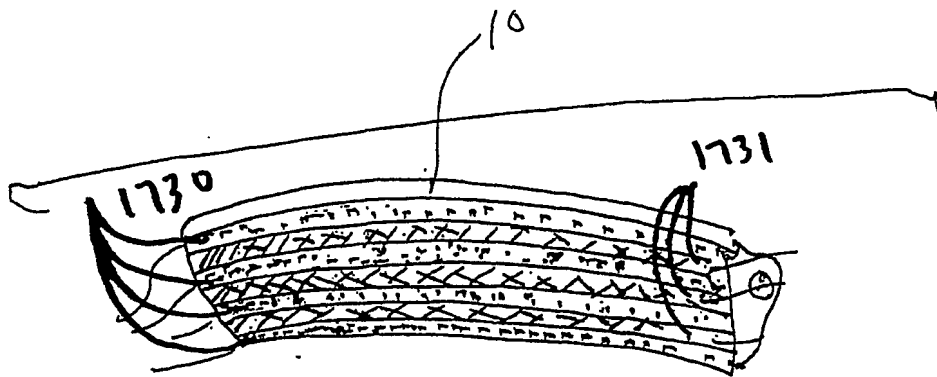


Fig. 173

(Acon)

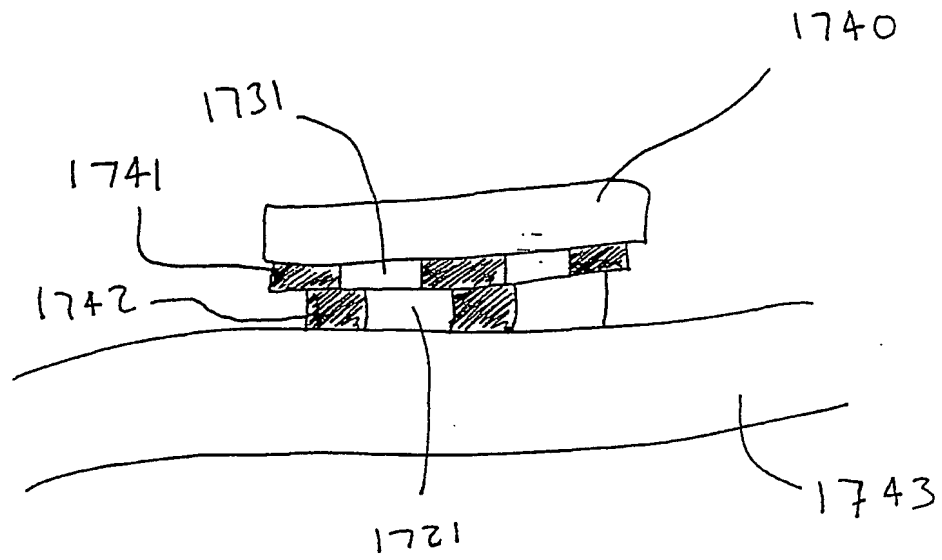


Fig. 174

(Acorn)



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WO 01/95830 A2

(54) Title: CARDIAC DISEASE TREATMENT AND DEVICE

(57) Abstract: A jacket of biological compatible material has an internal volume dimensioned for an apex of the heart to be inserted into the volume and for the jacket to be slipped over the heart. The jacket has a longitudinal dimension between upper and lower ends sufficient for the jacket to surround a lower portion of the heart with the jacket surrounding a valvular annulus of the heart and further surrounding the lower portion to cover at least the ventricular lower extremities of the heart. The jacket is adapted to be secured to the heart with the jacket surrounding at least the valvular annulus and the ventricular lower extremities. The jacket is adjustable on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain circumferential expansion of the heart beyond the maximum adjusted volume during diastole and to permit unimpeded contraction of the heart during systole.

**CARDIAC DISEASE TREATMENT AND DEVICE**

This application is being filed as a PCT application by ACORN  
CARDIOVASCULAR, INC., a United States national and resident, designating all  
5 countries except US.

**Field of the Invention**

The present invention pertains to a device and method for treating heart  
disease. More particularly, the present invention is directed to a method and device  
10 for treating congestive heart disease and related valvular dysfunction.

**Background of the Invention**

Congestive heart disease is a progressive and debilitating illness. The  
disease is characterized by a progressive enlargement of the heart.

15 As the heart enlarges, the heart is performing an increasing amount of work  
in order to pump blood each heart beat. In time, the heart becomes so enlarged the  
heart cannot adequately supply blood. An afflicted patient is fatigued, unable to  
perform even simple exerting tasks and experiences pain and discomfort. Further, as  
the heart enlarges, the internal heart valves cannot adequately close. This impairs  
20 the function of the valves and further reduces the heart's ability to supply blood.

Causes of congestive heart disease are not fully known. In certain instances,  
congestive heart disease may result from viral infections. In such cases, the heart  
may enlarge to such an extent that the adverse consequences of heart enlargement  
continue after the viral infection has passed and the disease continues its  
25 progressively debilitating course.

Patients suffering from congestive heart disease are commonly grouped into  
four classes (i.e., Classes I, II, III and IV). In the early stages (e.g., Classes I and II),  
drug therapy is the commonly proscribed treatment. Drug therapy treats the  
symptoms of the disease and may slow the progression of the disease. Importantly,  
30 there is no cure for congestive heart disease. Even with drug therapy, the disease  
will progress. Further, the drugs may have adverse side effects.

Presently, the only permanent treatment for congestive heart disease is heart transplant. To qualify, a patient must be in the later stage of the disease (e.g., Classes III and IV with Class IV patients given priority for transplant). Such patients are extremely sick individuals. Class III patients have marked physical  
5 activity limitations and Class IV patients are symptomatic even at rest.

Due to the absence of effective intermediate treatment between drug therapy and heart transplant, Class III and IV patients will have suffered terribly before qualifying for heart transplant. Further, after such suffering, the available treatment is unsatisfactory. Heart transplant procedures are very risky, extremely invasive and  
10 expensive and only shortly extend a patient's life. For example, prior to transplant, a Class IV patient may have a life expectancy of 6 months to one-year. Heart transplant may improve the expectancy to about five years.

Unfortunately, not enough hearts are available for transplant to meet the needs of congestive heart disease patients. In the United States, in excess of 35,000  
15 transplant candidates compete for only about 2,000 transplants per year. A transplant waiting list is about 8 – 12 months long on average and frequently a patient may have to wait about 1 – 2 years for a donor heart. While the availability of donor hearts has historically increased, the rate of increase is slowing dramatically. Even if the risks and expense of heart transplant could be tolerated,  
20 this treatment option is becoming increasingly unavailable. Further, many patients do not qualify for heart transplant for failure to meet any one of a number of qualifying criteria.

Congestive heart failure has an enormous societal impact. In the United States alone, about five million people suffer from the disease (Classes I through IV  
25 combined). Alarming, congestive heart failure is one of the most rapidly accelerating diseases (about 400,000 new patients in the United States each year). Economic costs of the disease have been estimated at \$38 billion annually.

Not surprising, substantial effort has been made to find alternative treatments for congestive heart disease. Recently, a new surgical procedure has been  
30 developed. Referred to as the Batista procedure, the surgical technique includes dissecting and removing portions of the heart in order to reduce heart volume. This is a radical, new and experimental procedure subject to substantial controversy.

Furthermore, the procedure is highly invasive, risky and expensive and commonly includes other expensive procedures (such as a concurrent heart valve replacement). Also, the treatment is limited to Class IV patients and, accordingly, provides no hope to patients facing ineffective drug treatment prior to Class IV. Finally, if the  
5 procedure fails, emergency heart transplant is the only available option.

Clearly, there is a need for alternative treatments applicable to both early and later stages of the disease to either stop the progressive nature of the disease or more drastically slow the progressive nature of congestive heart disease. Unfortunately, currently developed options are experimental, costly and problematic.

10 Cardiomyoplasty is a recently developed treatment for earlier stage congestive heart disease (e.g., as early as Class III dilated cardiomyopathy). In this procedure, the latissimus dorsi muscle (taken from the patient's shoulder) is wrapped around the heart and chronically paced synchronously with ventricular systole. Pacing of the muscle results in muscle contraction to assist the contraction of the  
15 heart during systole.

While cardiomyoplasty has resulted in symptomatic improvement, the nature of the improvement is not understood. For example, one study has suggested the benefits of cardiomyoplasty are derived less from active systolic assist than from remodeling, perhaps because of an external elastic constraint. The study suggests an  
20 elastic constraint (i.e., a non-stimulated muscle wrap or an artificial elastic sock placed around the heart) could provide similar benefits. Kass et al., *Reverse Remodeling From Cardiomyoplasty In Human Heart Failure: External Constraint Versus Active Assist*, 91 Circulation 2314 – 2318 (1995).

Even though cardiomyoplasty has demonstrated symptomatic improvement,  
25 studies suggest the procedure only minimally improves cardiac performance. The procedure is highly invasive requiring harvesting a patient's muscle and an open chest approach (i.e., sternotomy) to access the heart. Furthermore, the procedure is expensive -- especially those using a paced muscle. Such procedures require costly pacemakers. The cardiomyoplasty procedure is complicated. For example, it is  
30 difficult to adequately wrap the muscle around the heart with a satisfactory fit. Also, if adequate blood flow is not maintained to the wrapped muscle, the muscle may necrose. The muscle may stretch after wrapping reducing its constraining benefits

and is generally not susceptible to post-operative adjustment. Finally, the muscle may fibrose and adhere to the heart causing undesirable constraint on the contraction of the heart during systole.

German Utility Model Patent Application DE 295 17 393 U1 describes a pericardium prosthesis made from a biocompatible, non-expansible material, or at least hardly expansible material which surrounds the heart. While the pericardium prosthesis prevents overexpansion of the wall of the heart, the action is deployed suddenly when the volume of the heart reaches the volume enclosed by the prosthesis. The sudden deployment may adversely affect the heart.

PCT application WO 98/58598 describes an elastic pouch for at least partially enveloping a heart. The elastic pouch always exerts the same force, substantially irrespective of its expansion, on the heart, so that the heart is always relieved of substantially the same tension irrespective of its volume. The volume of the pouch in the unexpanded state is smaller than the volume of the heart at the stage of minimum filling, thereby ensuring that the pouch is in contact with the heart in all stages of expansion. While such a force may help eject blood during systole, such a force could interfere with ventricle filling during diastole.

Commonly assigned U.S. Patent No. 5,702,343 to Alferness dated December 30, 1997 (corresponding to PCT Published Application No. WO 98/14136) teaches a jacket to constrain cardiac expansion during diastole. The present invention pertains to improvements to the invention disclosed in the '343 patent.

### Summary of the Invention

According to a preferred embodiment of the present invention, a method and device are disclosed for treating congestive heart disease and related cardiac complications such as valvular disorders. The invention includes a jacket of biologically compatible material. The jacket defines an internal volume dimensioned for an apex of the heart to be inserted into the volume and for the jacket to be slipped over the heart. The jacket has a longitudinal dimension between upper and lower ends sufficient for the jacket to surround a lower portion of the heart preferably between, or even including the valvular annulus of the heart and the ventricular lower extremities. The jacket is adjustable on the heart to snugly

conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain circumferential expansion of the heart beyond the maximum adjusted volume during diastole and to permit unimpeded contraction of the heart during systole.

- 5           The jacket is preferably constructed from a flexible material having a multi-axial expansion less than about 30% when said material is exposed to a load up to about 5 pounds per inch (9 Newtons per centimeter). More preferably, the expansion of the material along a first axis is between about 30% and 40% when exposed to a uniaxial load between about 0.1 pounds per inch (0.2 Newtons per
- 10 centimeter) to about 0.5 pounds per inch (0.9 Newtons per centimeter) with no lateral constraint and the expansion of the material along a second axis perpendicular to the first axis of said material is between about 20% and 30% when exposed to a uniaxial load between about 0.1 pounds per inch (0.2 Newtons per centimeter) to about 0.5 pounds per inch (0.9 Newtons per centimeter) with no lateral constraint.
- 15 Most preferably, the jacket material is oriented such a that the first axis (i.e., the more compliant direction) extends parallel to the longitudinal axis (AA-BB) of the heart.

#### **Brief Description of the Drawings**

- 20           Fig. 1 is a schematic cross-sectional view of a normal, healthy human heart shown during systole;

Fig. 1A is the view of Fig. 1 showing the heart during diastole;

Fig. 1B is a view of a left ventricle of a healthy heart as viewed from a septum and showing a mitral valve;

- 25           Fig. 2 is a schematic cross-sectional view of a diseased human heart shown during systole;

Fig. 2A is the view of Fig. 2 showing the heart during diastole;

Fig. 2B is the view of Fig. 1B showing a diseased heart;

- Fig. 3 is a perspective view of a first embodiment of a cardiac constraint
- 30 device according to the present invention;

Fig. 3A is a side elevation view of a diseased heart in diastole with the device of Fig. 3 in place;

Fig. 4 is a perspective view of a second embodiment of a cardiac constraint device according to the present invention;

Fig. 4A is a side elevation view of a diseased heart in diastole with the device of Fig. 4 in place;

5 Fig. 5 is a cross-sectional view of a device of the present invention overlying a myocardium and with the material of the device gathered for a snug fit;

Fig. 6 is an enlarged view of a knit construction of the device of the present invention in a rest state;

Fig. 7 is a schematic view of the material of Fig. 6;

10 Fig. 8 shows a Force-Displacement plot of a material suitable for use in the jacket of the invention;

Fig. 9 shows comparative Force-Displacement plots for material suitable for use in the jacket of the invention, an elastic material and a non-elastic material;

15 Fig. 10 is a Force-Strain plot of material suitable for use in the jacket of the invention in which the load is exerted uniaxially, along both a first axis and second axis of the fabric and multiaxially;

Fig. 11 is a photograph of the material from Fig. 10, loaded along the second axis of the material at points A<sub>C</sub>, B<sub>C</sub>, C<sub>C</sub> and D<sub>C</sub>;

20 Fig. 12 is a photograph of the material from Fig. 10 loaded along the first axis of the material at points A<sub>L</sub>, B<sub>L</sub>, C<sub>L</sub> and D<sub>L</sub>;

Fig. 13 is a photograph of a variety of materials;

Fig. 14 is a Force-Strain plot of the uniaxial compliance for the materials shown in Fig. 13'

25 Fig. 15 is a Force-Strain plot of the multiaxial compliance for the materials shown in Fig. 13'

Fig. 16 is an illustrative Stress-Strain plot showing a linear elastic slope according to Hooke's Law;

Fig. 17 is an illustrative Stress-Strain plot showing the area of resilience and the elastic limit of a material;

30 Fig. 18 is an illustration of a fiber in which the overlapping filaments are substantially aligned with the fiber axis F-F;

Fig. 19 is an illustration of a fiber in which the overlapping filaments are not substantially aligned with the fiber axis F-F;

Fig. 20 is an illustration of a fiber which is composed of continuous filaments;

5 Fig. 21 is an example of a Force-Strain plot for a spherical shaped heart with multiaxial loading of material suitable for use in the jacket of the invention; and

Fig. 22 is an example of a Force-Strain plot for a cylindrical shaped heart with uniaxial loading of material suitable for use in the jacket of the invention.

## 10 Detailed Description of the Invention

### Congestive Heart Disease

With initial reference to Figs. 1 and 1A, a normal, healthy human heart H' is schematically shown in cross-section and will now be described in order to facilitate an understanding of the present invention. In Fig. 1, the heart H' is shown during  
15 systole (i.e., high left ventricular pressure). In Fig. 1A, the heart H' is shown during diastole (i.e., low left ventricular pressure).

The heart H' is a muscle having an outer wall or myocardium MYO' and an internal wall or septum S'. The myocardium MYO' and septum S' define four internal heart chambers including a right atrium RA', a left atrium LA', a right  
20 ventricle RV' and a left ventricle LV'. The heart H' has a length measured along a longitudinal axis AA' - BB' from an upper end or base B' to a lower end or apex A'.

The right and left atria RA', LA' reside in an upper portion UP' of the heart H' adjacent the base B'. The right and left ventricles RV', LV' reside in a lower portion LP' of the heart H' adjacent the apex A'. The ventricles RV', LV' terminate at  
25 ventricular lower extremities LE' adjacent the apex A' and spaced therefrom by the thickness of the myocardium MYO'.

Due to the compound curves of the upper and lower portions UP', LP', the upper and lower portions UP', LP' meet at a circumferential groove commonly referred to as the A-V groove AVG'. Extending away from the upper portion UP'  
30 are a plurality of major blood vessels communicating with the chambers RA', RV', LA', LV'. For ease of illustration, only the superior vena cava SVC' and a left pulmonary vein LPV' are shown as being representative.



The heart H' contains valves to regulate blood flow between the chambers RA', RV', LA', LV' and between the chambers and the major vessels (e.g., the superior vena cava SVC' and a left pulmonary vein LPV'). For ease of illustration, not all of such valves are shown. Instead, only the tricuspid valve TV' between the  
 5 right atrium RA' and right ventricle RV' and the mitral valve MV' between the left atrium LA' and left ventricle LV' are shown as being representative.

The valves are secured, in part, to the myocardium MYO' in a region of the lower portion LP' adjacent the A-V groove AVG' and referred to as the valvular annulus VA'. The valves TV' and MV' open and close through the beating cycle of  
 10 the heart H'.

Figs. 1 and 1A show a normal, healthy heart H' during systole and diastole, respectively. During systole (Fig. 1), the myocardium MYO' is contracting and the heart assumes a shape including a generally conical lower portion LP'. During diastole (Fig. 1A), the heart H' is expanding and the conical shape of the lower  
 15 portion LP' bulges radially outwardly (relative to axis AA' – BB').

The motion of the heart H' and the variation in the shape of the heart H' during contraction and expansion is complex. The amount of motion varies considerably throughout the heart H', although the external dimension of the heart H' generally reduces from about 4% to about 10% from end diastole to end systole.  
 20 The motion includes a component which is parallel to the axis AA' – BB' (conveniently referred to as longitudinal expansion or contraction). The motion also includes a component perpendicular to the axis AA'-BB' (conveniently referred to as circumferential expansion or contraction).

Having described a healthy heart H' during systole (Fig. 1) and diastole (Fig. 1A), comparison can now be made with a heart deformed by congestive heart  
 25 disease. Such a heart H is shown in systole in Fig. 2 and in diastole in Fig. 2A. All elements of diseased heart H are labeled identically with similar elements of healthy heart H' except only for the omission of the apostrophe in order to distinguish diseased heart H from healthy heart H'.

Comparing Figs. 1 and 2 (showing hearts H' and H during systole), the lower  
 30 portion LP of the diseased heart H has lost the tapered conical shape of the lower portion LP' of the healthy heart H'. Instead, the lower portion LP of the diseased

heart H bulges outwardly between the apex A and the A-V groove AVG. So deformed, the diseased heart H during systole (Fig. 2) resembles the healthy heart H' during diastole (Fig. 1A). During diastole (Fig. 2A), the deformation is even more extreme.

5       As a diseased heart H enlarges from the representation of Figs. 1 and 1A to that of Figs. 2 and 2A, the heart H becomes a progressively inefficient pump. Therefore, the heart H requires more energy to pump the same amount of blood. Continued progression of the disease results in the heart H being unable to supply  
10       adequate blood to the patient's body and the patient becomes symptomatic insufficiency. In contrast to a healthy heart H', the external dimension of the diseased heart H generally reduces from about 4% to about 6% from end diastole to end systole.

For ease of illustration, the progression of congestive heart disease has been illustrated and described with reference to a progressive enlargement of the lower  
15       portion LP of the heart H. While such enlargement of the lower portion LP is most common and troublesome, enlargement of the upper portion UP may also occur.

In addition to cardiac insufficiency, the enlargement of the heart H can lead to valvular disorders. As the circumference of the valvular annulus VA increases, the leaflets of the valves TV and MV may spread apart. After a certain amount of  
20       enlargement, the spreading may be so severe the leaflets cannot completely close (as illustrated by the mitral valve MV in Fig. 2A). Incomplete closure results in valvular regurgitation contributing to an additional degradation in cardiac performance. While circumferential enlargement of the valvular annulus VA may contribute to valvular dysfunction as described, the separation of the valve leaflets is  
25       most commonly attributed to deformation of the geometry of the heart H. This is best described with reference to Figs. 1B and 2B.

Figs. 1B and 2B show a healthy and diseased heart, respectively, left ventricle LV', LV during systole as viewed from the septum (not shown in Figs. 1B and 2B). In a healthy heart H', the leaflets MVL' of the mitral valve MV' are urged  
30       closed by left ventricular pressure. The papillary muscles PM', PM are connected to the heart wall MYO', MYO, near the lower ventricular extremities LE', LE. The papillary muscles PM', PM pull on the leaflets MVL', MVL via connecting chordae

tendineae CT', CT. Pull of the leaflets by the papillary muscles functions to prevent valve leakage in the normal heart by holding the valve leaflets in a closed position during systole. In the significantly diseased heart H, the leaflets of the mitral valve may not close sufficiently to prevent regurgitation of blood from the ventricle LV to the atrium during systole.

As shown in Fig. 1B, the geometry of the healthy heart H' is such that the myocardium MYO', papillary muscles PM' and chordae tendineae CT' cooperate to permit the mitral valve MV' to fully close. However, when the myocardium MYO bulges outwardly in the diseased heart H (Fig. 2B), the bulging results in displacement of the papillary muscles PM. This displacement acts to pull the leaflets MVL to a displaced position such that the mitral valve cannot fully close.

Having described the characteristics and problems of congestive heart disease, the treatment method and apparatus of the present invention will now be described.

#### Jacket

In general, the device of the invention comprises a jacket configured to surround the myocardium MYO. As used herein, "surround" means that the jacket provides reduced expansion of the heart wall during diastole by applying constraining surfaces at least at diametrically opposing aspects of the heart. In some preferred embodiments disclosed herein, the diametrically opposed surfaces are interconnected, for example, by a continuous material that can substantially encircle the external surface of the heart.

With reference now to Figs. 3, 3A, 4 and 4A, the device of the present invention is shown as a jacket 10 of flexible, biologically compatible material. As used herein, the term "biologically compatible material" refers to material that is biologically inert such that the material does not adversely affect the surrounding tissue, for example, by eliciting excessive or injurious rejection responses, inflammation, infarction, necrosis, etc.

The jacket 10 is an enclosed material having upper and lower ends 12, 14. The jacket 10, 10' defines an internal volume 16, 16' which is completely enclosed but for the open ends 12, 12' and 14'. In the embodiment of Fig. 3, lower end 14 is

closed. In the embodiment of Fig. 4, lower end 14' is open. In both embodiments, upper ends 12, 12' are open. Throughout this description, the embodiment of Fig. 3 will be discussed. Elements in common between the embodiments of Figs. 3 and 4 are numbered identically with the addition of an apostrophe to distinguish the second  
5 embodiment and such elements need not be separately discussed.

The jacket 10 is dimensioned with respect to a heart H to be treated. Specifically, the jacket 10 is sized for the heart H to be constrained within the volume 16. The jacket 10 can be slipped around the heart H. The jacket 10 has a length L between the upper and lower ends 12, 14 sufficient for the jacket 10 to  
10 constrain the lower portion LP. The upper end 12 of the jacket 10 extends at least to the valvular annulus VA and further extends to the lower portion LP to constrain at least the lower ventricular extremities LE.

The volume 16 defined by the jacket 10 is preferably substantially the same size as or larger than the volume of the heart H, in particular the lower portion LP of  
15 the heart, at the completion of systolic contraction such that the jacket 10 exerts no or only a slight pressure on the heart at end systole. Preferably, the pressure on the heart at end systole is no more than 10 mm Hg (1.3 kPa), more preferably no more than 5 mm Hg (0.66 kPa), most preferably no more than 2 mm Hg (0.27 kPa).

Generally, the jacket 10 is adjusted to a snug fit encompassing the external  
20 volume of the heart H during diastole such that the jacket 10 constrains enlargement of the heart H during diastole without significantly assisting contraction during systole. The amount of assistance during systole can be characterized by the pressure exerted by the jacket 10 on the heart H during systole. A jacket 10 that does not significantly assist contraction during systole will not exert significant  
25 pressure on the heart H at completion of systolic contraction.

If the enlargement of the external dimension of the heart H is considered to be zero percent (0%) at completion of systole (end systole) and one hundred percent (100%) at completion of diastole (end diastole), the jacket 10 preferably exerts pressure between about 4 mm Hg (0.53 kPa) and 40 mm Hg (5.3 kPa), more  
30 typically between about 4 mm Hg (0.53 kPa) and 20 mm Hg (2.7 kPa) when the enlargement of the external dimension of the heart is between 50% and 100%. In contrast, when the enlargement of the external dimension of the heart H is below

50%, it is preferred that the jacket 10 exert a pressure between about 2 mmHg (0.27 kPa) and about 20 mmHg (2.7 kPa), preferably no more than 10 mm Hg (1.3 kPa) on the heart H. It is noted that a jacket 10 that exerts a higher pressure (e.g., closer to 40 mm Hg (5.3 kPa)) at end diastole is likely to exert a higher pressure (e.g., closer to 10 mm Hg (1.3 kPa)) at end systole than a jacket that exerts a lower pressure (e.g., closer to 5 mm Hg (0.66 kPa)) at end diastole.

Since enlargement of the lower portion LP is most troublesome, in a preferred embodiment, the jacket 10 may be sized so that the upper end 12 can reside in the A-V groove AVG. Where it is desired to constrain enlargement of the upper portion UP, the jacket 10 may be extended to cover the upper portion UP.

Sizing the jacket 10 for the upper end 12 to terminate at the A-V groove AVG is desirable for a number of reasons. First, the groove AVG is a readily identifiable anatomical feature to assist a surgeon in placing the jacket 10. By placing the upper end 12 in the A-V groove AVG, the surgeon is assured the jacket 10 will provide sufficient constraint at the valvular annulus VA. The A-V groove AVG and the major vessels act as natural stops for placement of the jacket 10 while assuring coverage of the valvular annulus VA. Using such features as natural stops is particularly beneficial in minimally invasive surgeries where a surgeon's vision may be obscured or limited.

When the parietal pericardium is opened, the lower portion LP is free of obstructions for applying the jacket 10 over the apex A. If, however, the parietal pericardium is intact, the diaphragmatic attachment to the parietal pericardium inhibits application of the jacket over the apex A of the heart. In this situation, the jacket can be opened along a line extending from the upper end 12' to the lower end 14' of jacket 10'. The jacket can then be applied around the pericardial surface of the heart and the opposing edges of the opened line secured together after placed on the heart. Systems for securing the opposing edges are disclosed in, for example, U.S. Patent No. 5,702,343, the entire disclosure of which is incorporated herein by reference. The lower end 14' can then be secured to the diaphragm or associated tissues using, for example, sutures, staples, etc.

In the embodiment of Figs. 3 and 3A, the lower end 14 is closed and the length L is sized for the apex A of the heart H to be received within the lower end 14

when the upper end 12 is placed at the A-V groove AVG. In the embodiment of Figs. 4 and 4A, the lower end 14' is open and the length L' is sized for the apex A of the heart H to protrude beyond the lower end 14' when the upper end 12' is placed at the A-V groove AVG. The length L' is sized so that the lower end 14' extends  
5 beyond the lower ventricular extremities LE such that in both of jackets 10, 10', the myocardium MYO surrounding the ventricles RV, LV is in direct opposition to material of the jacket 10, 10'. Such placement is desirable for the jacket 10, 10' to present a constraint against enlargement of the ventricular walls of the heart H.

After the jacket 10 is positioned on the heart H as described above, the jacket  
10 10 is secured to the heart. Preferably, the jacket 10 is secured to the heart H through sutures. The jacket 10 is sutured to the heart H at suture locations S circumferentially spaced along the upper end 12. While a surgeon may elect to add additional suture locations to prevent shifting of the jacket 10 after placement, the number of such locations S is preferably limited so that the jacket 10 does not  
15 restrict contraction of the heart H during systole.

To permit the jacket 10 to be easily placed on the heart H, the volume and shape of the jacket 10 are larger than the lower portion LP during diastole. So sized, the jacket 10 may be easily slipped around the heart H. Once placed, the jacket's volume and shape are adjusted for the jacket 10 to snugly conform to the external  
20 geometry of the heart H during diastole. Such sizing is easily accomplished due to the construction of the jacket 10. For example, excess material of the jacket 10 can be gathered and sutured S" (Fig. 5) to reduce the volume of the jacket 10 and conform the jacket 10 to the shape of the heart H during diastole. Such shape represents a maximum adjusted volume. The jacket 10 constrains enlargement of  
25 the heart H beyond the maximum adjusted volume while preventing restricted contraction of the heart H during systole. As an alternative to gathering of Fig. 5, the jacket 10 can be provided with other ways of adjusting volume. For example, as disclosed in U.S. Patent No. 5,702,343, the jacket can be provided with a slot. The edges of the slot can be drawn together to reduce the volume of the jacket.

30 The volume of the jacket can be adjusted prior to, during, or after application of the device to the heart. In one embodiment, the heart is treated with a therapeutic agent, such as a drug to decrease the size of the heart, prior to application of the

jacket. In this embodiment, the therapeutic agent acts to reduce the overall size of the heart prior to surgery, and the jacket is thereafter applied to the reduced heart. Alternatively, the present invention can be used to reduce heart size at the time of placement in addition to preventing further enlargement. For example, the device  
5 can be placed on the heart and sized snugly to urge the heart to a reduced size. More preferably, the heart size can be reduced at the time of jacket placement through drugs, for example dobutamine, dopamine or epinephrine or any other positive inotropic agents, or surgical procedure to reduce the heart size. The jacket of the present invention is then snugly placed on the reduced sized heart and constrains  
10 enlargement beyond the reduced size.

The jacket 10 is adjusted to a snug fit on the heart H during diastole. Care is taken to avoid tightening the jacket 10 too much such that cardiac function is impaired. During diastole, the left ventricle LV fills with blood. If the jacket 10 is too tight, the left ventricle LV may not adequately expand and left ventricular  
15 pressure will rise. During the fitting of the jacket 10, the surgeon can monitor left ventricular pressure. For example, a well-known technique for monitoring so-called pulmonary wedge pressure uses a catheter placed in the pulmonary artery. The wedge pressure provides an indication of filling pressure in the left atrium LA and left ventricle LV. While minor increases in pressure (e.g., 1 mm Hg (0.13 kPa) to 3  
20 mm Hg (0.40 kPa) can be tolerated, the jacket 10 is snugly fit on the heart H but not so tight as to cause a significant increase in left ventricular pressure during diastole.

Furthermore, because the wall of the right ventricle RV tends to be thinner than the wall of the left ventricle LV and the pressure in the right ventricle RV tends to be lower than the pressure in the left ventricle LV, the pressure exerted by the  
25 jacket 10 on the heart H is preferably not greater than the end diastolic pressure of the right ventricle RV. If the pressure exerted by the jacket 10 is greater than the pressure of the right ventricle RV, expansion and/or filling of the right ventricle RV may be compromised. Generally, a jacket 10 that imposes between about a 5% to about a 10% reduction in maximum diastolic volume serves to reduce cardiac  
30 volume without compromising cardiac function. Generally, excessive pressure exerted by the jacket 10 on the heart H results in decreased cardiac output, increased central venous pressure, and/or decreased systolic pressure.

The jacket 10 can be used in early stages of congestive heart disease. For patients facing heart enlargement due to viral infection, the jacket 10 permits constraint of the heart H for a sufficient time to permit the viral infection to pass. In addition to preventing further heart enlargement, the jacket 10 treats valvular disorders by constraining circumferential enlargement of the valvular annulus and deformation of the ventricular walls, causing displacement of the papillary muscles PM and chordae tendineae CT. Preventing displacement of these heart elements is important for allowing the leaflets MVL to fully close.

The fabric 18 of the jacket 10 is preferably tear and run resistant. In the event of a material defect or inadvertent tear, such a defect or tear is restricted from propagation by reason of the knit construction.

#### Material

Preferably the jacket 10 is constructed from a compliant, biocompatible material. As used herein, the term "compliant" refers to a material that can expand in response to a force. "Compliance" refers to the displacement (in inches or centimeters) or strain (inches/inch or cm/cm) per a unit load (in pounds or kilograms) or load per unit width (in pounds per inch or kilograms per centimeter) for a material. "Elasticity" refers to the ability of the deformed material to return to its initial state after the deforming load is removed.

The compliance of the device is influenced by the fabric stitch and fabrication processing as well as interaction with the tissue after implantation. The multiaxial expansion of the material is generally less than about 30%, more typically less than about 25%, most typically between about 10% and 20% as the material is exposed to a load up to about 5 pounds per inch (9 N/cm) more typically between about 1 pound per inch (1.8 N/cm) and 3 pounds per inch (5 N/cm). As used herein, the term "uniaxial expansion" refers to the expansion of a material along only one axis. The term "biaxial expansion" refers to the expansion of a material along a first axis and a second axis, typically the second axis is perpendicular to the first axis. The term "multiaxial expansion" refers expansion of a material along at least a first and a second axis and includes expansion along more than two axes.



The compliance of the material allows the jacket to be implanted without gaps and an insignificant load at end diastole. The compliance of the device along with the compliance of the heart allows the device to conform nicely to the irregular and unique shape of each heart.

5        Fig. 8 is a graph generated from data of a ball burst test using a 1.75 inch diameter test area of sample material from the jacket of the invention. The test was performed according to ASTM D3787-89. According to this test, a ball is pressed against the center of the material with a measured force. As the load on the material is increased from 0 pounds (0 Newtons) to 36 pounds (160 Newtons), the material  
10        expands multiaxially. The initial part of the curve, up to about 5 pounds (22 Newtons) and 0.30 in (0.76 cm) deformation, has a shallow (somewhat horizontal) slope. As the load is increased above 5 pounds (22 Newtons), the slope becomes more steep (i.e., more vertical). At a load of just over 36 pounds (160 Newtons), the fabric reaches its load capacity and fails.

15        The force exerted by the heart during diastolic filling is small, e.g., less than 5 pounds (22 Newtons) of equivalent burst load. The normal diastolic load is more typically equivalent to a 1 to 3 pound (4 to 13 Newtons) ball burst load. Therefore, in use, the multiaxial expansion of the jacket 10 material remains within the shallow part of the curve. At maximum diastole; further expansion of the heart is resisted by  
20        the increasing slope of the compliance curve.

Fig. 9 compares the compliance of the jacket of the invention with a pouch constructed from a non-compliant material, such as described in DE 295 17 393 (Hohmann), and a pouch constructed from an elastic material, such as described in PCT WO 98/58598 (Haindl).

25        Hohmann describes a pouch which is non-expansible. The pouch described by Hohmann does not materially present a resisting force during diastole nor does the pouch materially provide an assisting force during systole. In Fig. 9, the Hohmann material is shown in an idealized form where the pouch has no force on the heart ("zero force region") until maximum diastolic filling, where the pouch does  
30        not expand ("expansion limit").

Haindl describes a pouch that is smaller than the smallest volume of the heart and exerts a constant force on the heart which increases as the heart volume

increases. As shown in Fig. 9, the material of Haindl has a progressively increasing force on the heart ("elastic region") until maximum diastolic filling, when the pouch becomes inelastic ("inelastic region") preventing further expansion.

In contrast to the pouch described by Hohmann, the material used in the jacket of the invention is compliant rather than elastic. In contrast to the pouch described by Haindl, the jacket of the invention does not apply a significant or constant force on the heart H throughout the cardiac cycle. Instead, the jacket 10 of the invention generally applies a greater pressure (e.g., about 6 mm Hg (0.8 kPa) to about 36 mm Hg (4.8 kPa) more pressure) on the heart at end diastole than at end systole.

#### Compliance

Generally, the jacket 10 material is formed from intertwined fibers 20 which are made up of a plurality of filaments 30 (See, e.g., Figs. 6, 11 and 12). The compliance of the material may be due to a variety of factors, including, but not limited to, the compliance of the individual filaments 30 that make up the fibers 20, the relative movement of the filaments 30 within a fiber 20, and/or the relative movement of the intertwined fibers 20 when subjected to load.

Additionally, the compliance of the material may be affected by the shape of the heart, the manner in which the jacket 10 is fitted on the heart H and tissue fibrosis. Fibrosis tends to reduce the acute compliance of the material by preventing the openings of the fabric from geometrically changing shape.

The compliant nature of the jacket material can be easily contrasted with elastomeric material. Whereas the compliant material of the jacket preferably expands linearly up to about 30% to 50%, and elastically up to 70% without undergoing significant plastic deformation or failure, elastomeric material can be stretched repeatedly to at least twice its original length (200%), and upon release of the load, will return without force to its approximate original length. Rubber and spandex are examples of elastomeric materials. The force of the recoil depends upon the density of the elastomeric fibers within the material.

Compliance due to the relative movement (e.g., geometric deformation of the fabric openings) of the intertwined fibers 20 may be affected by the manner in which

the fibers 20 are entwined. For example, a knit material will tend to be more compliant than a woven material because the loops of the knit are capable of deforming (e.g., widening or lengthening) to accommodate applied stress. In comparison, woven materials tend to have less elongation unless elastomeric fibers are used. Knit material also tends to recover well from deformation because the loops attempt to return to their original positions. The looped configuration of the fibers accommodates this recovery more readily than does the interwoven configuration found in woven materials. The ease and quickness with which elastic recovery takes place is also dependent on the fiber composition. The fibers 20 of the jacket 10 material may be entwined as a knit (for example, a warp knit) or as a weave. Preferably, the fibers 20 of the jacket 10 material are entwined as a knit.

Compliance due to the relative movement of the intertwined fibers 20 can be observed by the deformation of the structure of the fibers 20 within the material. Compliance can also be characterized using MTS Sintech test equipment. At a given load, the strain refers to the percentage increase in length of the fabric in that direction with the load applied. Preferably, the internal volume 16 of the jacket 10 is capable of multiaxial expansion up to about 30%, more typically between about 10% and 20%, in response to a load or stress up to about 5 pounds per inch (9 N/cm) without significant plastic deformation or failure.

Fig. 10 is a plot showing the uniaxial compliance along a first axis and along a second axis perpendicular to the first axis and the multiaxial compliance of a material suitable for use in the jacket 10. The compliance parallel to the first axis of the fabric is slightly greater than the compliance perpendicular to the first axis (parallel to the second axis) of the fabric and the multiaxial compliance is significantly lower than either uniaxial compliance. Preferably, the first axis (with slightly greater compliance) is oriented longitudinally round the heart and the second axis (with slightly less compliance) is oriented circumferentially around the heart.

As shown in Fig. 10, between 20% and 40% strain, the slope of the compliance curve for the multiaxial case is 3 to 4 times greater than either uniaxial compliance curve. However, between 70% and 100% strain, the extrapolated multiaxial compliance curve slope is only 1.3 to 1.4 times greater than either uniaxial compliance curve. This indicates that the limiting stiffness of the fabric in

multiaxial or uniaxial loading is similar. However, strain to reach that constraint is dependent upon loading direction.

Compliance due to the relative movement of the intertwined fibers 20 under uniaxial tension with no lateral constraint is depicted in Figs. 11 and 12. Fig. 12 shows a knit exposed to a load in the first uniaxial direction, again with no lateral constraint (load is applied vertical with reference to the photograph). Fig. 11 shows the same knit exposed to a load in a second uniaxial direction (perpendicular to the load in Fig. 12) with no lateral constraint (load is applied horizontal with reference to the photograph). A comparison of Fig. 11 and 12 shows that the fabric compliance along one axis (vertical with reference to the photograph) of the fabric is greater than the compliance perpendicular to that axis (horizontal with reference to the photograph). Preferably, the uniaxial compliance along a first axis (with no lateral constraint) is between about 30% and 40% when exposed to a load between about 0.1 pounds per inch (0.2 N/cm) to about 0.5 pounds per inch (0.9 N/cm); between about 40% and 50% when exposed to a load between about 0.5 pounds per inch (0.9 N/cm) to 1.0 pounds per inch (1.8 N/cm); and between about 50% and 60% when exposed to a load between about 1.0 pounds per inch (1.8 N/cm) and 1.5 pounds per inch (2.6 N/cm). Preferably, the uniaxial strain along a second axis of the fabric (perpendicular to the first axis, with no lateral constraint) is about 20% to about 30% when exposed to a load between about 0.1 pounds per inch (0.2 N/cm) to about 0.5 pounds per inch (0.9 N/cm); about 30% and 40% when exposed to a load between about 0.5 pounds per inch (0.9 N/cm) to about 1.0 pounds per inch (1.8 N/cm); and between about 40% and 50% when exposed to a load between about 1.0 pounds per inch (1.8 N/cm) and 1.5 pounds per inch (2.6 N/cm).

Four locations (A, B, C and D) are identified on both uniaxial curves in Fig. 10. These locations correspond approximately to the loads applied to the fabric in the photos of Figs. 11 and 12. For both uniaxial directions, as the fabric load increases from  $A_C$  to  $D_C$  and from  $A_L$  to  $D_L$  the compliance curve is fairly flat. The load is predominantly accommodated by linearization of filament 30 and fiber 20 crimp and geometric distortion of the knit pattern. The photos in Figs. 11 and 12 illustrate the distortion of the knit fabric as the openings in the fabric collapse. For example, the looping configuration of a warp knit allows the openings to collapse

more along a first axis (e.g., along the warp direction) as compared to a second axis, perpendicular to the first axis (e.g., along the weft direction). This is the reason for the slightly greater compliance in the warp direction. Beyond points  $D_c$  and  $D_L$ , the fabric becomes less compliant due to little remaining geometric distortion. The compliance curves become linear and nearly parallel to each other beyond about 80% strain. The compliance in this portion of each curve is primarily due to the elongation of the poly(ethylene terephthalate) (e.g., polyester) filaments in the fibers after the filament crimp has been removed.

As shown in Fig. 10, multiaxial loading of the fabric causes the fabric to be generally less compliant due to the inability of the fabric to geometrically deform. The multiaxial compliance of the jacket material up to 12% strain is essentially linear. The slight nonlinear portion of the curve is primarily due to yarn crimp and tightening of the loops that form the geometric structure. Beyond about 12% strain, the curve is linear and is controlled by the elongation of the filaments within the fiber. Generally, the slope of the compliance curve is 30% to 40% less compliant than either of the uniaxial compliance curves.

Preferably, the knit is a so-called "Atlas knit" well known in the fabric industry. The Atlas knit is described in Paling, Warp Knitting Technology, p. 111, Columbine Press (Publishers) Ltd., Buxton, Great Britain (1970). The Atlas knit is a knit of fibers having directional expansion properties. As shown in Figs. 6, 11 and 12, the intertwined fibers include a plurality of longitudinally extending filaments 30, wherein opposing surfaces of said multi-filament fibers 20 define a cell structure. The fibers 20 of the fabric 18 are woven into two sets of fiber strands 21a, 21b having longitudinal axes  $X_a$  and  $X_b$ . The strands 21a, 21b are interlaced to form the fabric 18 with strands 21a generally parallel and spaced apart and with strands 21b generally parallel and spaced apart.

For ease of illustration, fabric 18 is schematically shown in Fig. 7 with the axis of the strands 21a, 21b only being shown. The strands 21a, 21b are interlaced with the axes  $X_a$  and  $X_b$  defining a diamond-shaped open cell 23 having diagonal axes  $A_m$ . In a preferred embodiment, the axes  $A_m$  are 5 mm in length when the fabric 18 is at rest and not stretched. The fabric 18 can stretch in response to a force. For any given force, the fabric 18 stretches most when the force is applied parallel to the

diagonal axes  $A_m$ . The fabric 18 stretches least when the force is applied parallel to the strand axes  $X_a$  and  $X_b$ . The jacket 10 is constructed for the material of the knit to be directionally aligned for a diagonal axis  $A_m$  to be parallel to the heart's longitudinal axis AA-BB.

5           Fig. 6 illustrates the knit 18 in a rest state. Figs. 11 and 12 illustrate a knit exposed to a variety of loads in a first uniaxial direction (Fig. 12), or a second uniaxial direction (Fig. 11), perpendicular to the first uniaxial direction. The directional compliance of the knit material is apparent from a comparison of Fig. 11 and Fig. 12 (e.g., a load in one direction does not produce the same strain as a load  
10 in the perpendicular direction).

Fig. 13 displays photographs of a variety of fabrics: (A) a knit fabric (thickness: 0.018 in.) suitable for use in the jacket of the invention; (B) a monofilament polypropylene mesh fabric (thickness: 0.026 in.), commercially available under the name Marlex (C.R. Bard, Inc., New Jersey); (C) a polyester  
15 mesh (thickness: 0.008 in.), commercially available under the name Lars Mesh (Meadox of Boston Scientific); (D) a stretch polyester fabric (thickness: 0.027 in.), commercially available as Meadox from Boston Scientific; and (E) a double velour material (thickness: 0.048 in.), commercially available under the name Cooley Double Velour (Meadox of Boston Scientific). The results of uniaxial and  
20 multiaxial compliance testing of these materials are shown in Figs. 14 and 15, respectively.

In Fig. 14, the Marlex, Lars and double velour are less compliant under uniaxial tension while the fabric with a uniaxial compliance most similar to the material used in the jacket 10 of the invention is the Meadox stretch polyester. It is  
25 slightly more compliant than either uniaxial strains of the material used in the jacket 10 at low stress. At high stress, the stretch polyester has a compliance slope nearly parallel and offset by about 5% to the right of the second axis uniaxial curve of the fabric used in the jacket 10 of the invention.

The five fabrics were also tested under multiaxial loading and the compliance  
30 is plotted in Fig. 15. Under multiaxial loading the Meadox stretch polyester shows the greatest compliance. The slope of the curve at about 12% strain is nearly four times greater for the fabric used in the jacket 10 of the invention than the slope for

the stretch polyester. The multiaxial compliance of the other three commercial fabrics are again much stiffer and nearly indistinguishable from one another. They all have compliance curves that are more than double the stiffness of the fabric used in the jacket 10 of the invention at low strain. None of the commercial fabrics tested  
5 provide desirable levels of compliance for both uniaxial and multiaxial loading, yet provide the constraining support required at higher strains to prevent continued heart dilation for this application. Only the stretch polyester appears to have compliance that is similar to the jacket 10 fabric, allowing conformance to the heart. However, at larger strains the stretch polyester does not stiffen under multiaxial loads like the  
10 fabric used in the jacket 10, resulting in less constraining support.

The knit material has numerous advantages. Such a material is flexible to permit unrestricted movement of the heart H (other than the desired constraint on circumferential expansion). The material is open defining a plurality of interstitial spaces for fluid permeability as well as minimizing the amount of surface area of  
15 direct contact between the heart H and the material of the jacket 10 (thereby minimizing areas of irritation or abrasion) to minimize fibrosis and scar tissue.

The open areas of the knit construction also allows for electrical connection between the heart and surrounding tissue for passage of electrical current to and from the heart. For example, although the knit material is an electrical insulator, the  
20 open knit construction is sufficiently electrically permeable to permit the use of trans-chest defibrillation of the heart. Also, the open, flexible construction permits passage of electrical elements (e.g., pacer leads) through the jacket. Additionally, the open construction permits other procedures, e.g., coronary bypass, to be performed without removal of the jacket.

25 A large open area for cells 23 is desirable to minimize the amount of surface area of the heart H in contact with the material of the jacket 10 (thereby reducing fibrosis). However, if the cell area 23 is too large, localized aneurysm can form. Also, a strand 21a, 21b can overly a coronary vessel with sufficient force to partially block the vessel. A smaller cell size increases the number of strands thereby  
30 decreasing the restricting force per strand. In a preferred embodiment, the cell area CA of cells in a particular row directly correlates with a cross-sectional circumferential dimension of the heart that the row of cells surrounds relative to

other cross-sectional circumferential dimensions. That is, the greater the cross-sectional circumferential dimension, the greater the area of the cells in the row of cells directly overlying that cross-sectional circumferential dimension. By "correlating" cell area with cross-sectional circumferential dimension of the heart, the cell area is determined as a function of the cross-sectional circumferential dimension of the heart. The cell area is determined so that when the weave material is applied to the heart or is shaped into a jacket and applied to the heart, each cell can widen sufficiently to provide desirable cardiac constraint. Thus, the cell area will be smaller for cells in a row applied over a region of the heart that has a smaller cross-sectional circumferential dimension than the cell area of cells in a row applied over a region of the heart having a larger cross-sectional circumferential dimension. The appropriate maximum cell area may be, for example, 1 to 100 mm<sup>2</sup>, typically 16 to 85 mm<sup>2</sup>. The maximum cell area is the area of a cell 23 after the material of the jacket 10 is fully stretched and adjusted to the maximum adjusted volume on the heart H as previously described.

#### Young's Modulus

Prior to discussing the contribution of filament elasticity and fiber structure to the compliance of the jacket material, an overview of Young's Modulus will be provided.

Stress refers to the force (F) normalized by the cross sectional area (A) of an object. Stress can be represented by the following formula:  $F/A$ . For fabrics, unit load is commonly used in lieu of stress. The unit load is force (F) normalized by the width of a unit measure of fabric. Strain is defined as the change in length of the object normalized by the initial length. Strain can be represented by the following formula:  $(l_1 - l_0)/l_0$ . Thus, if stress (or unit load) is plotted versus strain, the slope of the line in the elastic/linear range of the material gives the elastic modulus or Young's modulus (E) of the object. (Fig. 16).

The stress-strain curve begins at zero stress and stops at the amount of force which ruptures the fiber. The shape, length and height of a stress-strain curve indicates how well a fiber resists elongation, how far it will elongate before



rupturing and how strong it is. The curve also establishes the point at which a fiber will not recover fully from an applied stress.

According to Hooke's law, (at relatively low stress) the strain is proportional to stress and therefore the ratio of the two is a constant that may be used to indicate the elasticity of the object. Young's Modulus may be loosely defined as the force required to elongate an object. The elastic modulus can be calculated from measurements obtained by pulling a sample of the object in a tensile testing machine. Young's Modulus for some polymers is provided in Table 1, below.

**Table 1. Young's Modulus for Some Polymers**

Material	Modulus (Kpsi)	Modulus (GPa)
Polyimides	400-700	3-5
Polyesters	150-700	1-5
Nylon	300-600	2-4
Polystyrene	400-500	3-3.4
Polyethylene	30-100	0.2-0.7

The linear portion of the curve generally indicates the elastic behavior of the material. Strains induced in the material due to a stress within the linear portion are totally recoverable once the stress is removed. The strain is thus referred to as elastic. When the initial linear segment of the stress-strain curve rises steeply, a relatively large increase in stress produces a relatively small increase in strain (e.g., the fiber has a high initial modulus). If the line slopes at 45°, then there is a unit increase in strain for each unit increase in stress and the initial modulus of the fiber is average. As the slope decreases or the line become more horizontal, the initial modulus of the fiber becomes lower. Fibers with low initial modulus are relatively easy to elongate. A slight force results in considerable fiber lengthening. In contrast, a large force must be applied to fibers with high initial modulus for small amounts of extension to occur.

In this initial segment of the stress-strain curve, the lengthening of the fiber is (1) the result of the degree to which polymers lying at angles to the fiber axis can be moved into alignment with the axis and (2) polymers with a nonlinear configuration can be straightened. Polymers that are spiraled and folded tend to act like springs; once stress is released they attempt to return to their original configuration. Thus,

low modulus fibers tend to be less oriented than high modulus fibers. Polymer slippage does not occur within the fiber during the initial modulus segment of the stress strain curve.

As the stress on an object is increased, the plot of stress versus strain becomes non-linear (Fig. 17). The elastic limit generally refers to the point where the curve begins to deviate from linearity. Beyond the elastic limit, the material undergoes plastic deformation. Unlike elastic deformation, plastic deformation is not recoverable, i.e., the change is permanent. When a load is applied to an object and the object deforms and does not return to its original length when the load is removed, the object is said to have undergone a plastic deformation. At the elastic limit, the polymers of the object begin to slip by one another as the stress becomes larger than the force of attraction between the polymers. However, when polymers are covalently cross-linked, the crosslinks work to pull the polymers back their original positions.

#### Fibers

The compliance of the jacket 10 may also be affected by the relative movement of the filaments 30 within the fibers 20. The relative movement of the filaments 30, in turn, may be affected by the structure of the fiber 20. A fiber 20 may be composed of overlapping filaments 30 that are twisted about one another and held together by a binding mechanism (Figs. 18 and 19) or the fiber 20 may be composed of continuous filaments 30 (or a single filament) that extend longitudinally along the length of the fiber 20 (Fig. 20), assembled with or without a twist. The fiber 20 may be composed of filaments 30 that are substantially aligned with the fiber axis F-F (Fig. 18) or the filaments 30 may lie more obliquely with respect to the fiber 20 axis (Fig. 19).

Preferably, the fiber 20 is composed of continuous filaments 30. Because continuous filaments 30 have less protruding ends, continuous filaments 30 are less likely to abrade the surface of the heart H during systole and diastole. In a fiber made of continuous filaments 30, the lengthening of the fiber 20 is generally the result of the degree to which filaments 30 lying at angles to the fiber axis F-F can be moved into alignment with the axis F-F and filaments 30 with a nonlinear

configuration can be straightened. Filaments 30 that are spiraled and folded tend to act like springs; once stress is released they attempt to return to their original configuration. Overlapping filaments 30 in a fiber 20 may slip when exposed to stress, thus permanently altering or "stretching" the fiber 20.

5           Fibers 20 with multifilaments that are not substantially aligned are preferred, such that fabric compliance from the fiber straightening can help to accommodate expansion of the ventricles during diastole. Generally, preferred fibers include 70 Denier textured polyester.

10   Filaments

          The elasticity of the filaments 30 which make up the fibers 20 may also affect the compliance of the jacket 10. The filaments 30 are preferably formed of a non-elastomeric material (i.e., the filament 30 does not return to its approximate original length with force), preferably the filament is constructed from a material  
15   with a moderate modulus of elasticity, more preferably between 1.0 GPa (150 Kpsi) and 5 GPa (700 Kpsi). In a preferred embodiment, the filaments 30 include 34 strands to construct the 70 Denier poly(ethylene terephthalate) (e.g., polyester) fibers 20. While poly(ethylene terephthalate) is presently preferred, other suitable materials may include polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE),  
20   polypropylene, titanium and stainless steel.

          With the foregoing, a device and method have been taught to treat cardiac disease. The jacket 10 constrains further undesirable circumferential enlargement of the heart while not impeding other motion of the heart H. With the benefits of the present teachings, numerous modifications are possible. For example, the jacket 10  
25   need not be directly applied to the epicardium (i.e., outer surface of the myocardium) but could be placed over the parietal pericardium. Further, an anti-fibrosis lining (such as a PTFE coating on the fibers of the knit) could be placed between the heart H and the jacket 10. Alternatively, the fibers 20 can be coated with PTFE.

          The jacket 10 is low-cost, easy to place and secure, and is convenient for use  
30   in minimally invasive procedures. The thin, flexible fabric 18 permits the jacket 10 to be collapsed and passed through a small diameter tube in a minimally invasive procedure.

The jacket 10, including the knit construction, freely permits longitudinal and circumferential contraction of the heart H (necessary for heart function). Unlike a solid wrap (such as a muscle wrap in a cardiomyoplasty procedure), the fabric 18 does not impede cardiac contraction. After fitting, the jacket 10 is inelastic to prevent further heart enlargement while permitting unrestricted inward movement of the ventricular walls. Because the jacket 10 is not constructed from an elastomeric material, it does not substantially assist the heart during systolic contraction.

The open cell structure permits access to coronary vessels for bypass procedures subsequent to placement of the jacket 10. Also, in cardiomyoplasty, the latissimus dorsi muscle has a variable and large thickness (ranging from about 1 mm to 1 cm). The material of the jacket 10 is uniformly thin (less than 1 mm thick). The thin wall construction is less susceptible to fibrosis and minimizes interference with cardiac contractile function.

Animal test studies on the device show the efficacy of the invention. Test animals were provided with the device 10 of Fig. 3. The animals' hearts were rapidly paced to induce enlargement. After six weeks, animals without the device experienced significant heart enlargement while those with the device experienced no significant enlargement. Further, animals with the device had significantly reduced mitral valve regurgitation.

In addition to the foregoing, the present invention can be used to reduce heart size at the time of placement in addition to preventing further enlargement. For example, the device can be placed on the heart and sized snugly to urge the heart to a reduced size. More preferably, the heart size can be reduced at the time of jacket placement through drugs (e.g., dobutamine, dopamine or epinephrine or any other positive inotropic agents) to reduce the heart size. The jacket of the present invention is then snugly placed on the reduced sized heart and prevents enlargement beyond the reduced size.

From the foregoing, a low cost, reduced risk method and device are taught to treat cardiac disease. The invention is adapted for use with both early and later stage congestive heart disease patients. The invention reduces the enlargement rate of the heart as well as reducing cardiac valve regurgitation.

### Examples of Implant Scenarios

#### Example 1

In this example, the heart is assumed to be spherical in shape and 46 cm (18 in.) in diameter at end diastole. The device is installed around the heart and adjusted to create a uniform loading of the fabric. Because the heart is spherical in shape, the pressure is uniformly applied to the heart and resisted by the device like a spherical pressure vessel, where the load per unit width is  $pd/4$  (Note:  $p$  = pressure,  $d$  = diameter). Since the load is uniform the multiaxial compliance curve of the fabric would be most applicable. Fig. 21 illustrates the installed condition for an end diastolic device pressure of 20 mm Hg (2.7 kPa). This corresponds to 0.6 lbs/in. fabric load for this size heart.

During systole the heart muscle contracts and the external dimension is reduced. On average, the heart reduces circumferentially by approximately 6% and longitudinally by 4% from end diastole to end systole. Thus, for the case of a 4% to 5% change in circumference and diameter is assumed. This linear dimensional change relates to a 12% to 15% external ventricular volume change for a spherical heart. At end systole, Fig. 21 shows that the circumference reduces to 44 cm (17.3 in.) and the applied pressure drops from 20 mm Hg (2.7 kPa) to 4 mm Hg (0.53 kPa). For this condition the fabric load is only 0.1 lbs/in and the device is nearly unloaded.

The pressure applied by the device is helping to offload heart wall stress throughout the cardiac cycle. This support is greatest at end diastole when the heart volume is greatest (relaxing between systolic contractions). Although the diastolic phase is considered relaxing, the myocardium may never actually completely relax. Some slight loading during diastole may not significantly restrict filling but rather serve to off load the wall stress throughout the cardiac cycle.

If the heart becomes improved and reduces in size, the device will become unloaded at end systole. Only a 16% volume reduction will result in the device being completely unloaded. If the heart continues to dilate due to continued disease progression, load support from the jacket increases dramatically. With less than 4% increase dilation, the applied pressure would double to a load of 40 mm Hg (5.3

kPa). The biaxial compliance curve of the fabric results in very significant pressure changes for relatively small volume changes.

### Example 2

5           In this example, the heart is assumed to be cylindrical in shape and again 46 cm (18 in.) in circumference at end diastole. The device is installed around the heart and adjusted to create a primarily circumferential loading of the fabric with the end effects and longitudinal loading assumed to be negligible. Because the heart is cylindrical in shape, the circumferential load per unit width is  $pd/2$ . Note that based  
10           on the pressure vessel theory, this is twice the load resisted in the spherical shape of Example 1 for the same pressure. Since the load is only circumferential, the uniaxial compliance curve of the fabric would be most applicable. Fig. 22 illustrates the installed condition for an end diastolic device pressure of 10 mm Hg (1.3 kPa). This corresponds to 0.6 pounds per inch (1.1 N/cm) fabric load for this size heart.

15           Similar to Example 1, during systole the heart muscle contracts and the external dimensions of the heart are reduced. If a 6% change in circumference and diameter is assumed, along with a 4% longitudinal length change, the external ventricular volume change would be approximately 17%. At end systole, Fig. 22 shows that the circumference reduces to 44 cm (17.3 in.) and the applied pressure  
20           only drops from 10 mm Hg (1.3 kPa) to 8 mm Hg (1.1 kPa). For this condition, the fabric load is nearly unchanged from 0.6 to 0.5 pounds per inch (1.1 N/cm to 0.88 N/cm). This small load change is due to a flat compliance curve.

            Similar to Example 1, the pressure applied by the device is helping to offload heart wall stress throughout the cardiac cycle. However, in this case the support  
25           from the jacket is nearly constant throughout the cardiac cycle.

            For the case shown in Fig. 22, if the heart becomes improved and reduces in size, the device will continue to be supported for a volume reduction of up to 70%. This compliance/load scenario would result in longer term support than in Example 1. As the heart diameter reduces and progresses to the left on the compliance curve,  
30           the loading is gradually lowered. This will continue until a very significant 70% external volume reduction occurs. If the heart continues to dilate due to continued disease progression or exercise overload, the load support from the jacket increases

dramatically with a significant increase in dilation. A 30 mm Hg (4 kPa) increase in pressure to the 40 mm Hg (5.3 kPa) design load will allow a 30% increase diametrical dilation. The uniaxial compliance curve of the fabric allows very large changes in size with relative small load changes, assuming the load remains

5 unidirectional.

The therapy provided by the device may be a combination of Examples 1 and 2. When installed the jacked behaves as in Example 1 if it is adjusted to provide a nearly uniform load. Then as the heart improves and reduces in size, the loading may become more unidirectional if either the longitudinal or circumferential

10 directions do not change at the same rate. This would change the compliance curve to behave more like Example 2. The actual fabric compliance curve may transition from multi-axial to uniaxial as the heart shape changes.

## WHAT IS CLAIMED IS:

1. A device for treating cardiac disease of a heart having a longitudinal axis from an apex to a base and having an upper portion and a lower portion  
5 divided by an A-V groove, said heart including a valvular annulus adjacent said A-V groove and ventricular lower extremities adjacent said apex, the device comprising:
  - a jacket of flexible material defining a volume between an open upper end and a lower end, wherein a multiaxial expansion of said flexible  
10 material is less than about 30 % when said material is exposed to a load up to about 5 pounds per inch (9 N/cm);
  - said jacket dimensioned for said apex of said heart to be inserted into said volume through said open upper end and for said jacket to be  
15 slipped over said heart, said jacket further dimensioned for said jacket to have a longitudinal dimension between said upper and lower ends sufficient for said jacket to constrain said lower portion with said jacket constraining said valvular annulus;
  - said jacket adapted to be secured to said heart with said jacket having  
20 portions disposed on opposite sides of the heart between said valvular annulus and said ventricular lower extremities; and
  - said jacket adapted to be adjusted on said heart to snugly conform to an external geometry of said heart and assume a maximum adjusted volume for said jacket to constrain circumferential expansion of said  
25 heart beyond said maximum adjusted volume during diastole and permit substantially unimpeded contraction of said heart during systole.
2. A device according to claim 1 wherein:
  - an expansion of said material along a first axis of said material is  
30 between about 30% and 40% when exposed to a uniaxial load between about 0.1 pounds per inch (0.2 N/cm) to about 0.5 pounds per inch (0.9 N/cm) with no lateral constraint;



- an expansion of said material along a second axis of said material is between about 20% and 30% when exposed to a uniaxial load between about 0.1 pounds per inch (0.2 N/cm) to about 0.5 pounds per inch (0.9 N/cm) with no lateral constraint; and
  - 5       - said material oriented for said second axis to extend circumferentially around said heart and wherein said first axis is perpendicular to second axis.
- 10       3.     A device according to claim 1 wherein said jacket is open at said lower end.
4.     A device according to claim 1 wherein said jacket is closed at said lower end.
5.     A device according to claim 1 wherein said material comprises intertwined fibers.
- 15       6.     A device according to claim 5 wherein said material is a knit material.
7.     A device according to claim 6 wherein said material is a warp knit.
- 20       8.     A device according to claim 6 wherein said material is an Atlas knit.
9.     A device according to claim 5 wherein said material is a weave.
- 25       10.    A device according to claim 5 wherein said intertwined fibers comprise a plurality of longitudinally extending filaments.
11.   A device according to claim 1 wherein said material is selected from a group of polytetrafluoroethylene, expanded polytetrafluoroethylene, polypropylene, poly(ethylene terephthalate), titanium or stainless steel.
- 30       12.   A device according to claim 1 wherein said material is formed of elongated fibers selected from a group of polytetrafluoroethylene, expanded

polytetrafluoroethylene, polypropylene, poly(ethylene terephthalate),  
titanium or stainless steel.

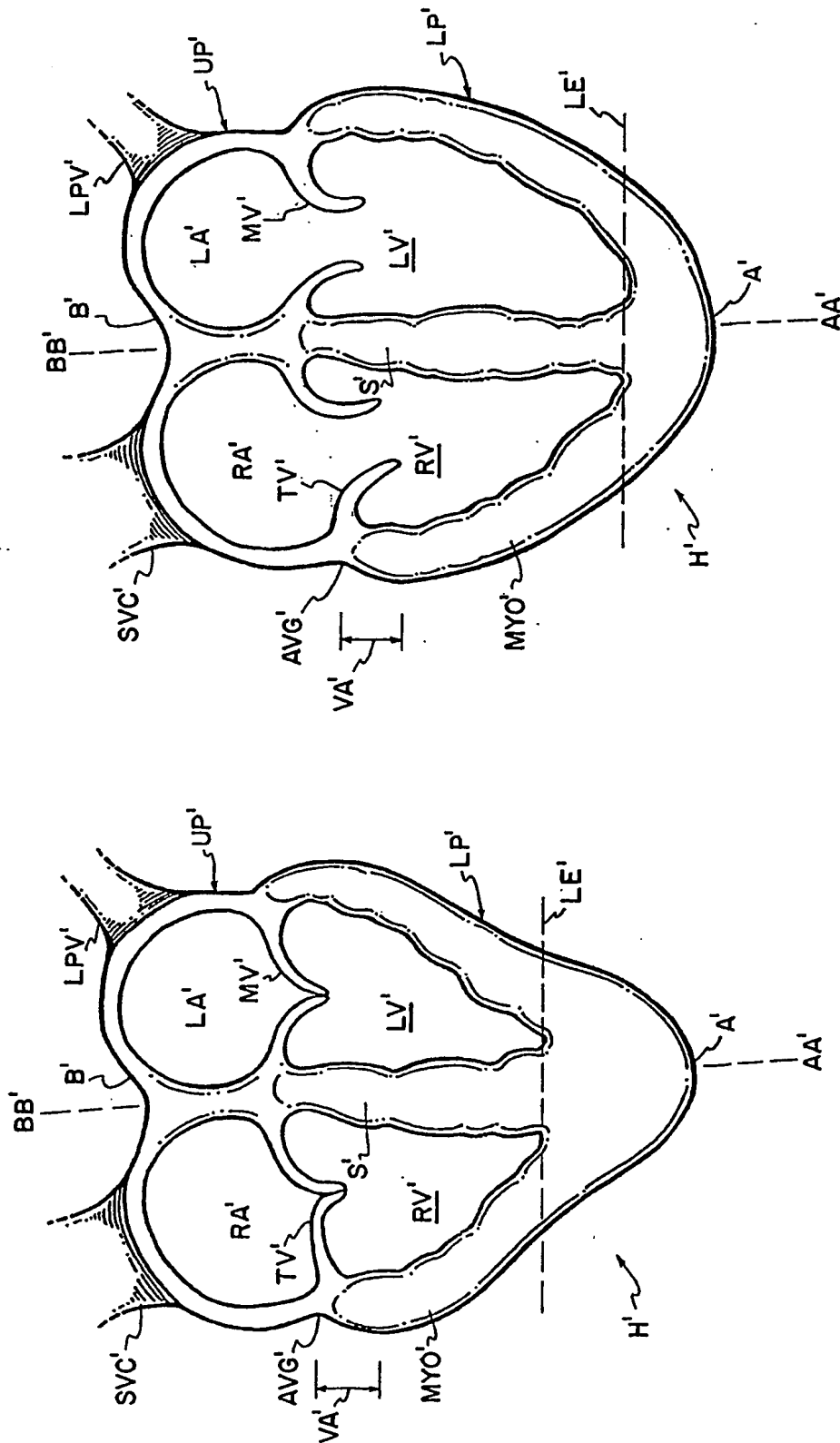


FIG. 1A

FIG. I

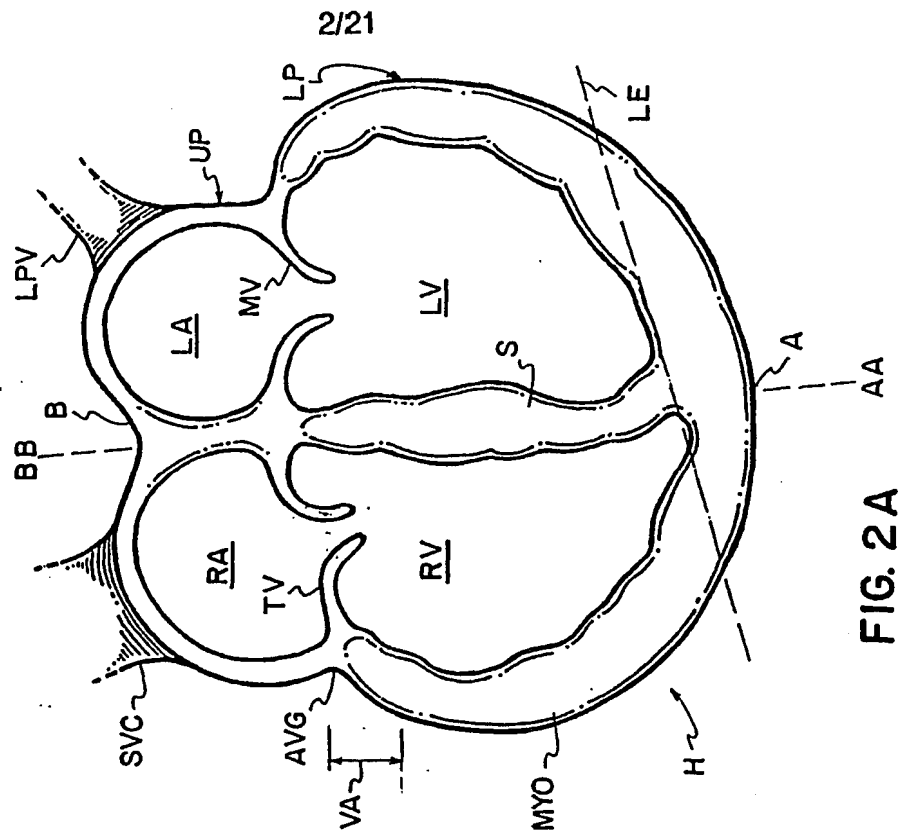


FIG. 2A

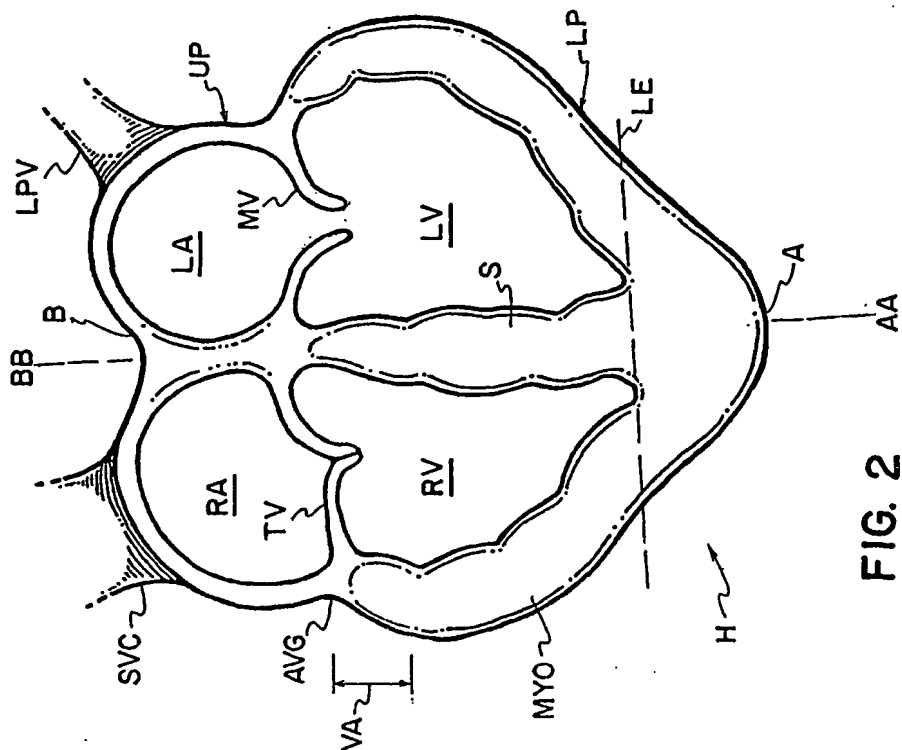


FIG. 2

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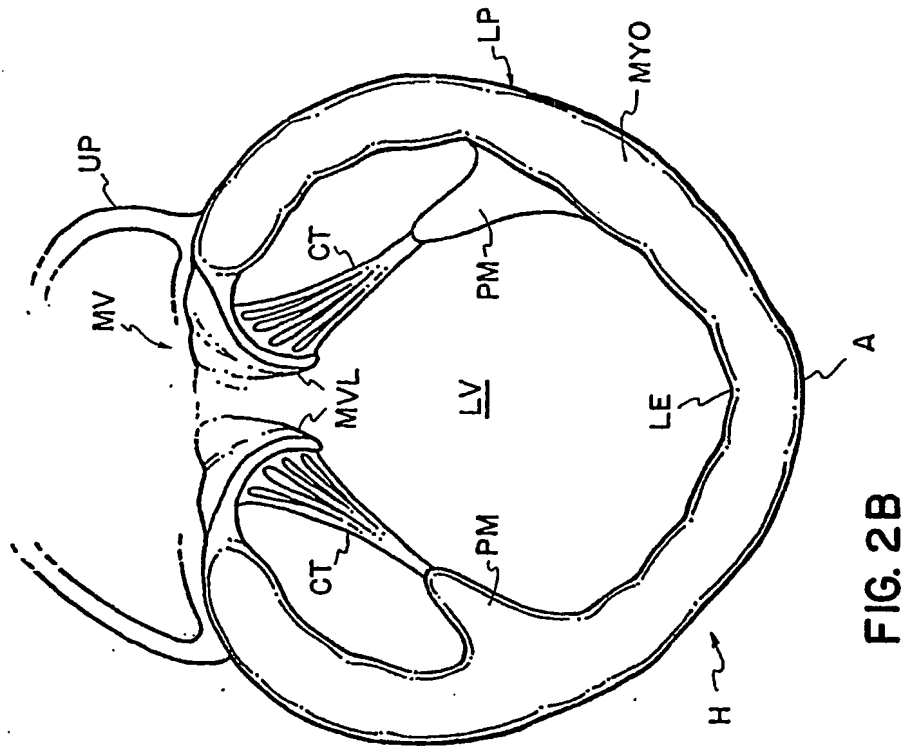


FIG. 2B

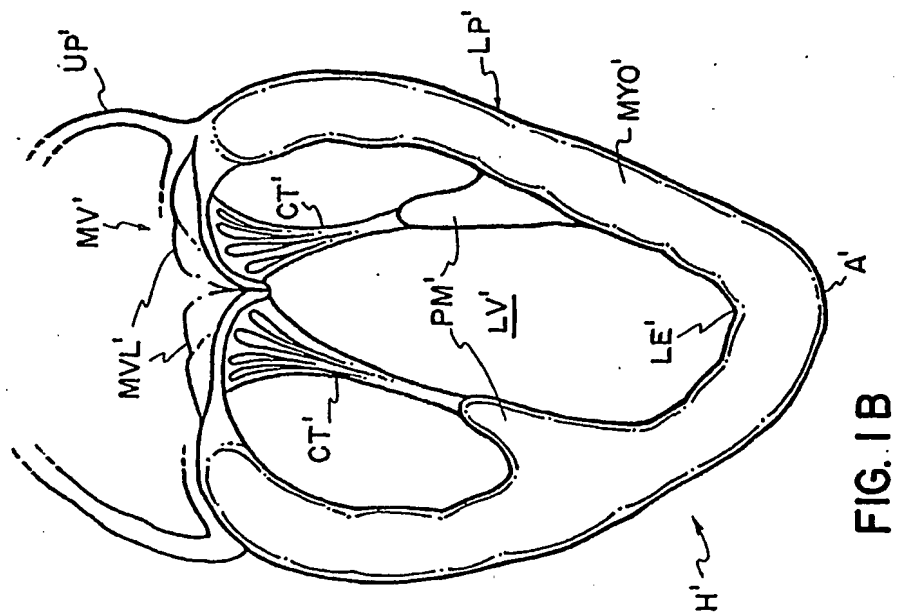


FIG. 1B

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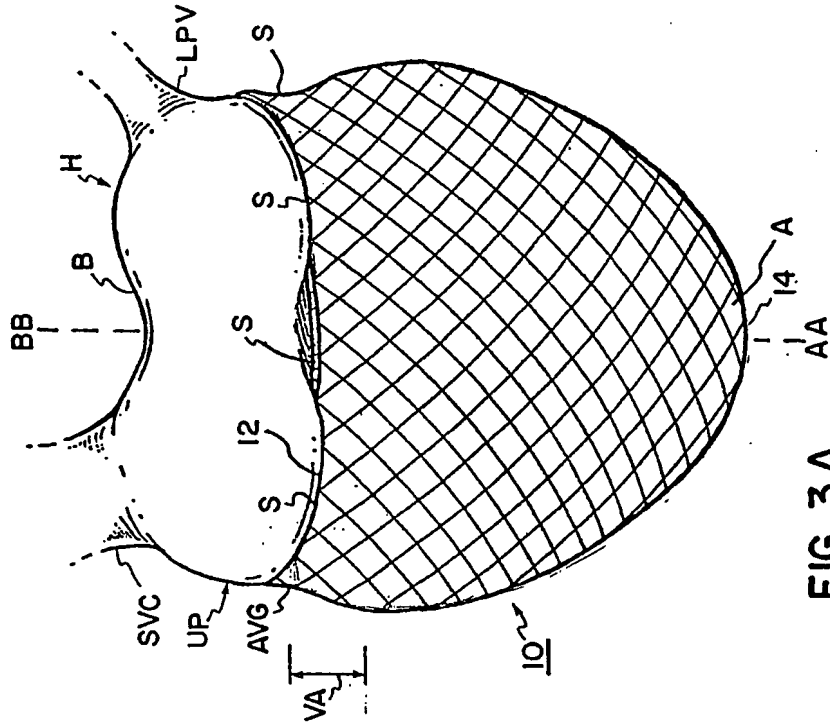


FIG. 3A

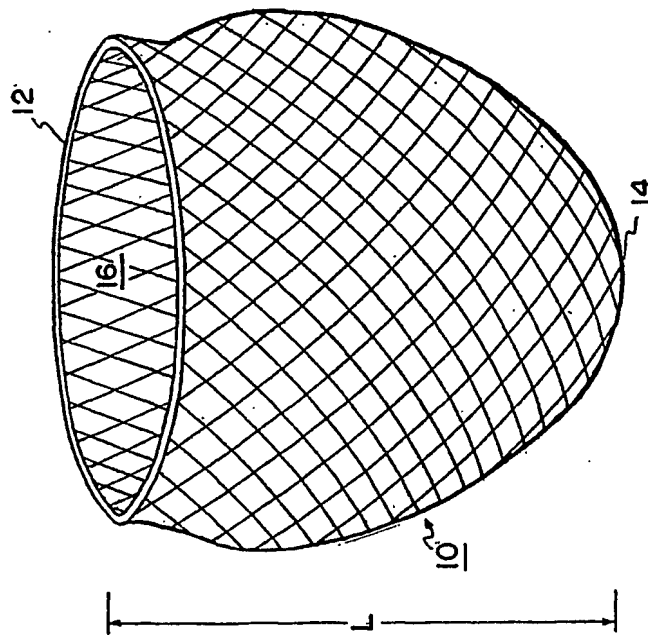


FIG. 3

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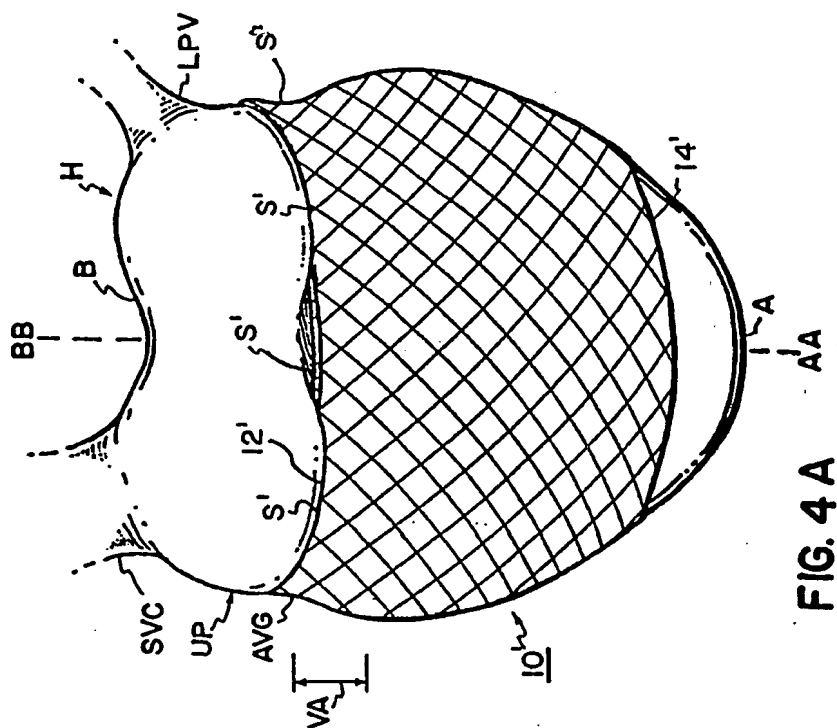


FIG. 4A

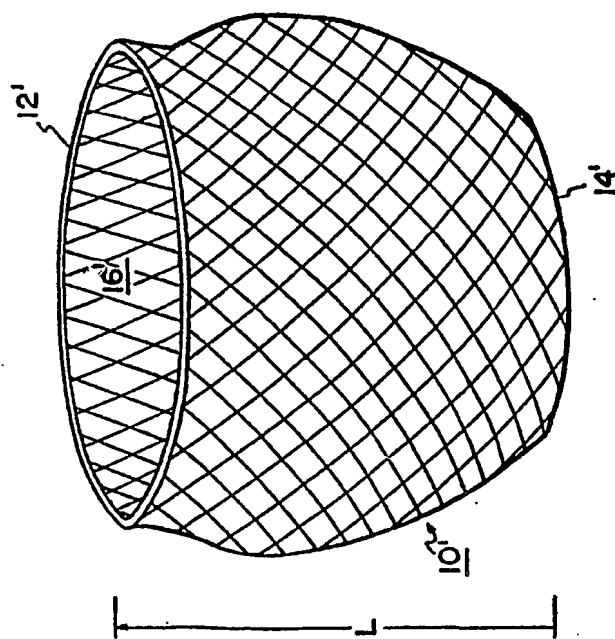


FIG. 4

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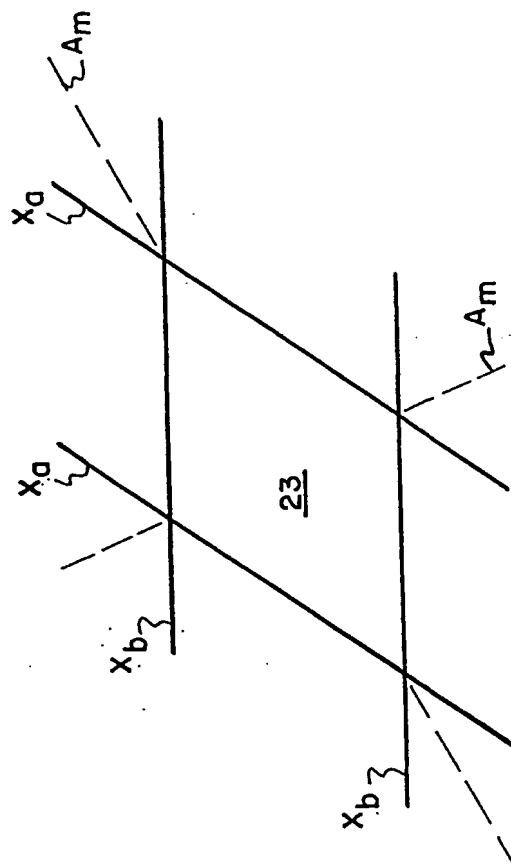


FIG. 7

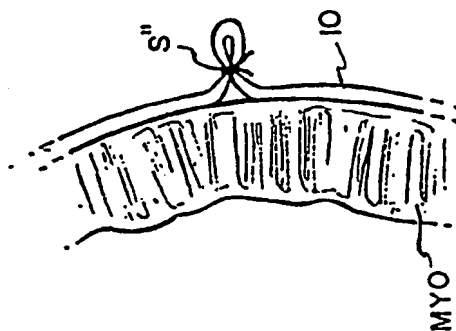
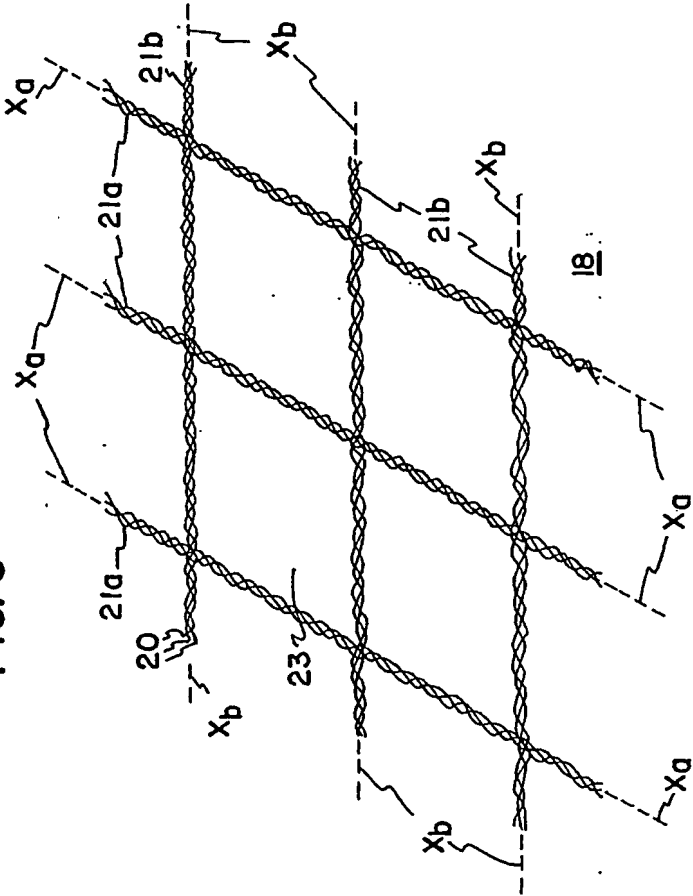


FIG. 5

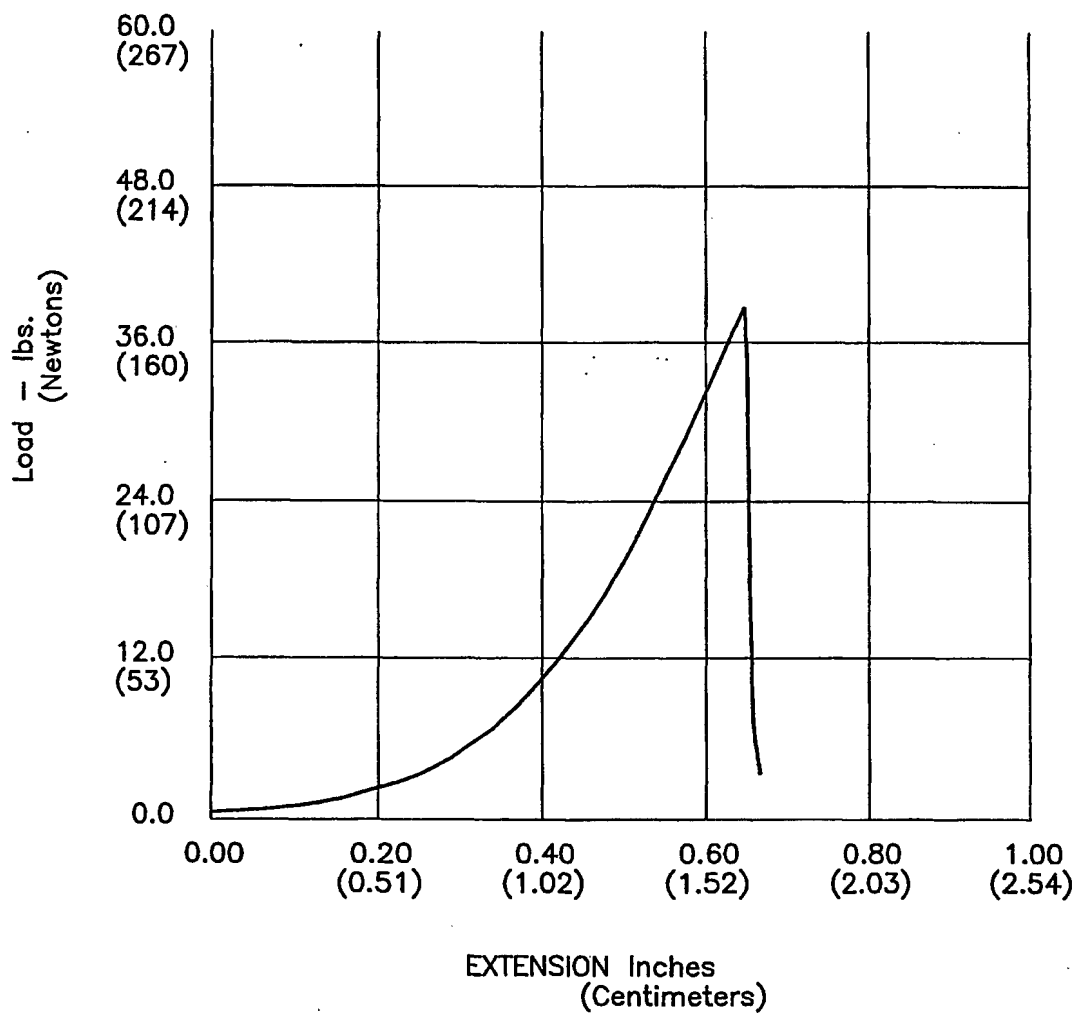


FIG. 6



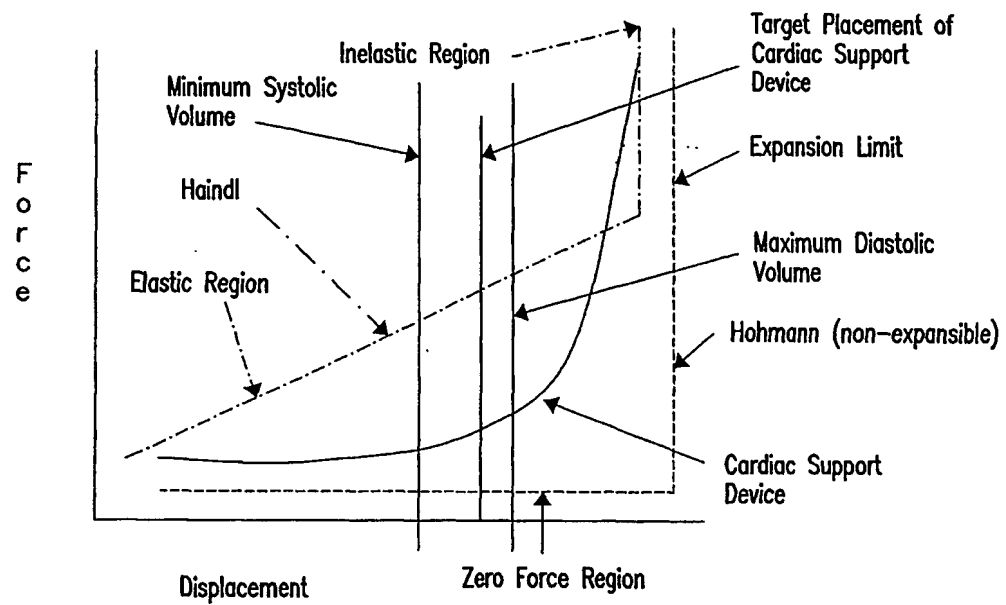
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FIG. 8



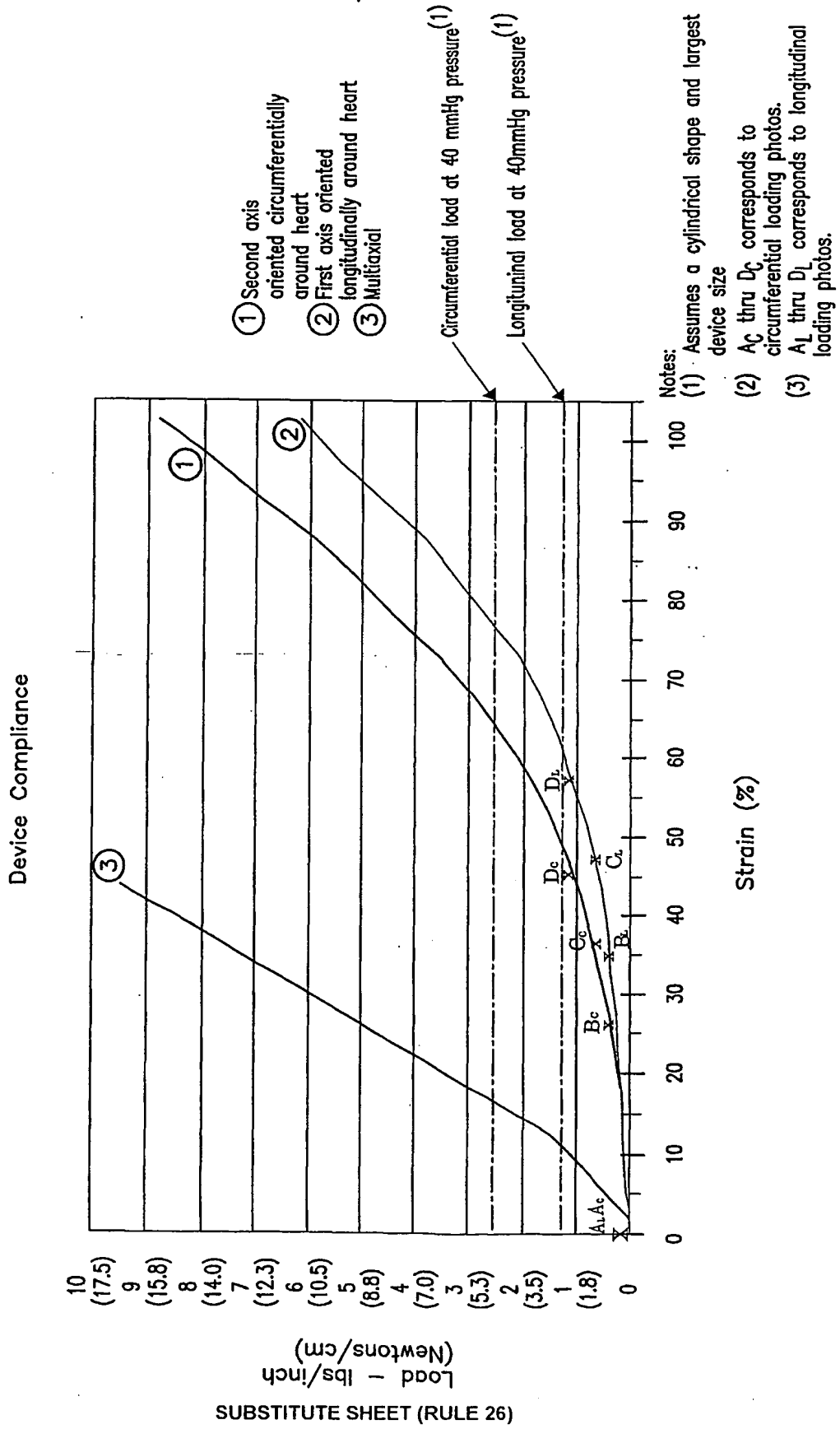
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FIG. 9



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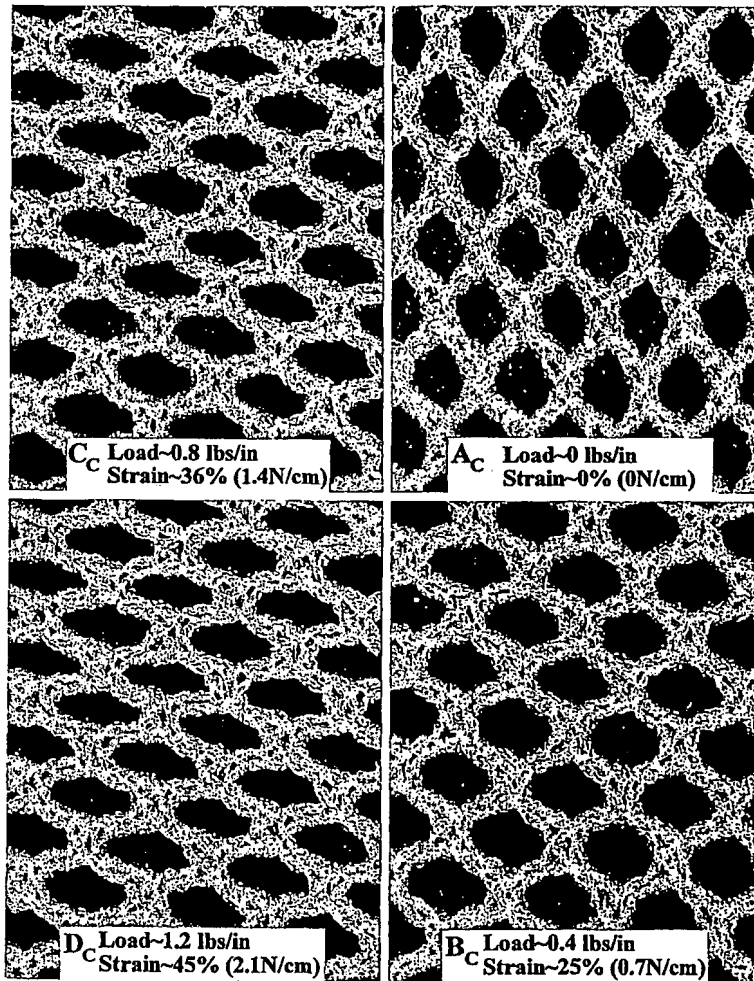
FIG. 10



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FIG. 11

Second Axis (12x)



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FIG. 12

First Axis (12x)

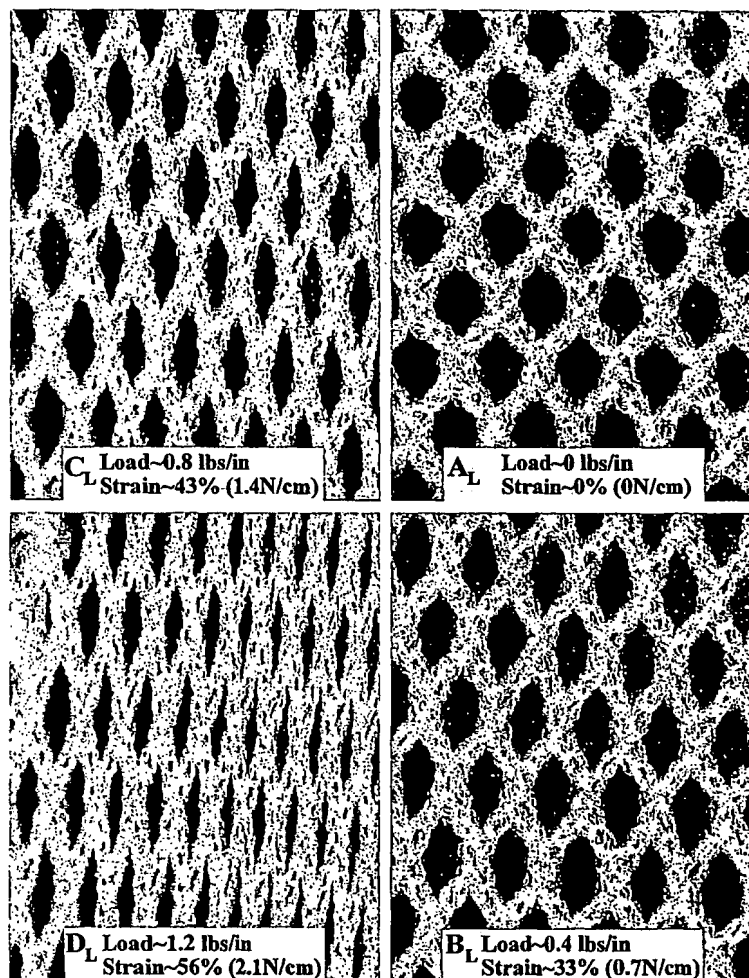


FIG. 13

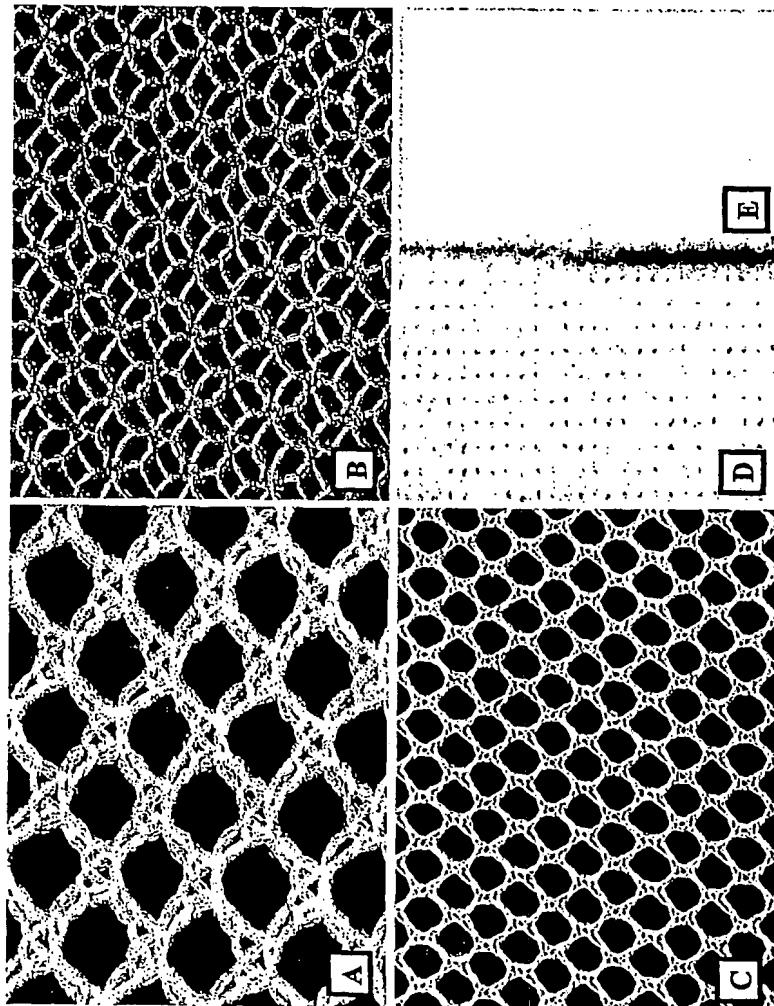


FIG. 14

Uniaxial Device Compliance vs.  
Commercially Available Fabrics

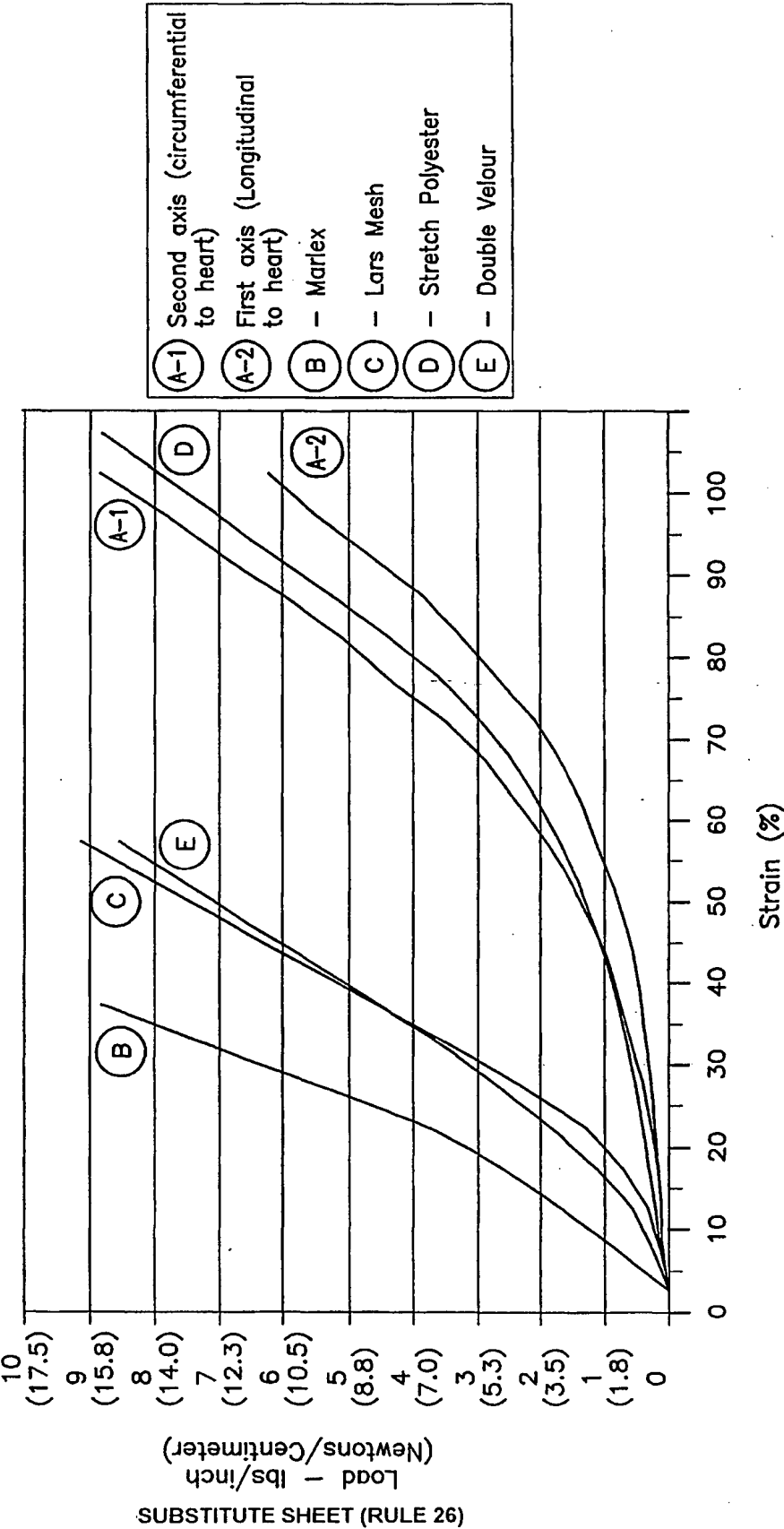
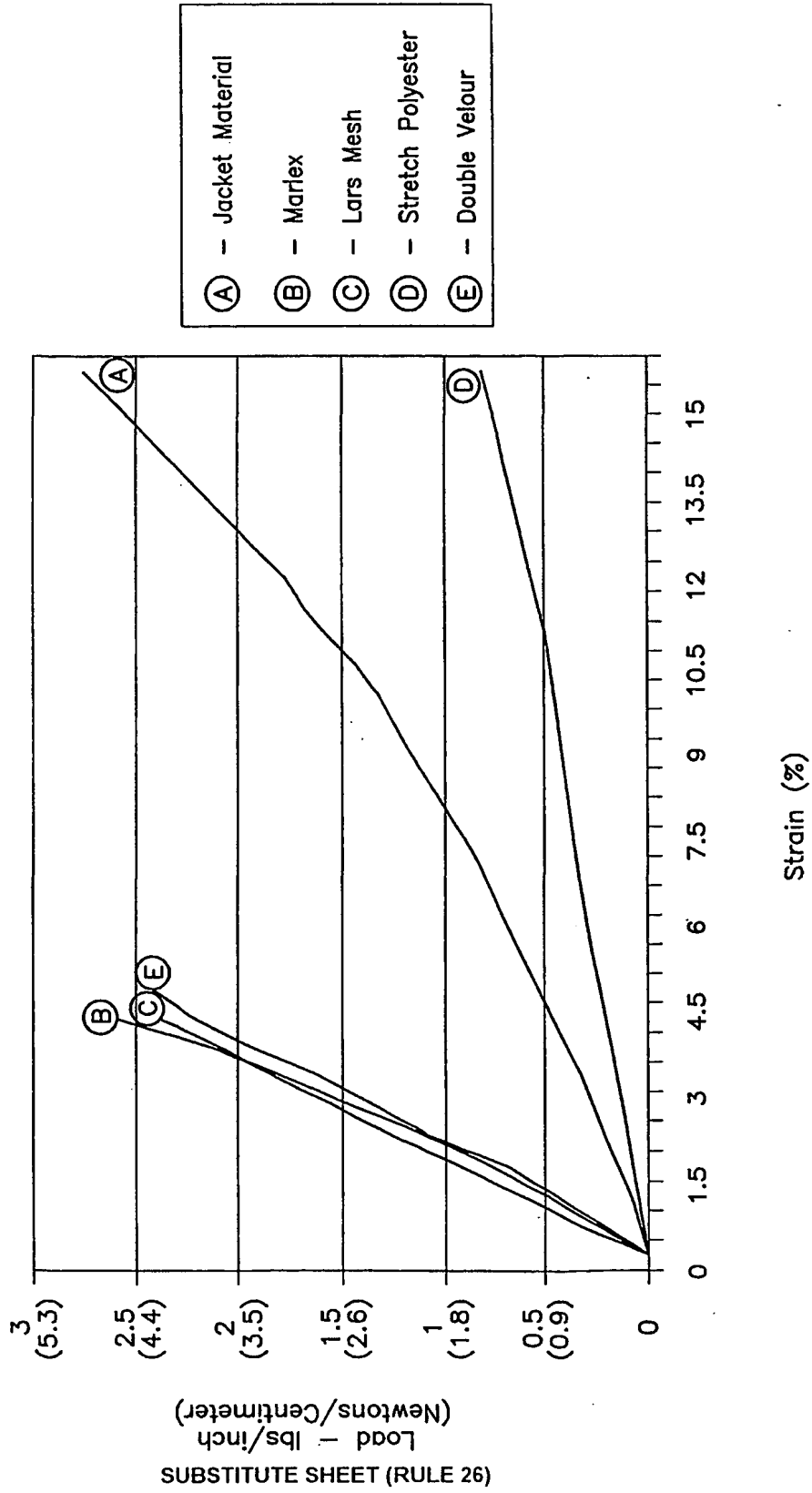




FIG. 15

Multiaxial Device Compliance vs.  
Commercially Available Fabrics



SUBSTITUTE SHEET (RULE 26)

FIG. 16

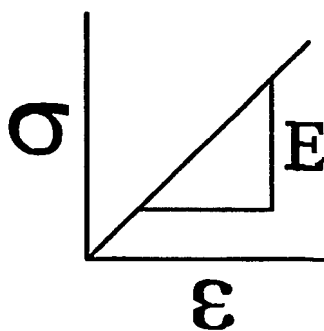


FIG. 17

- ⊗ Resilience — area under curve before elastic limit
- ⊙ Toughness — total area under curve

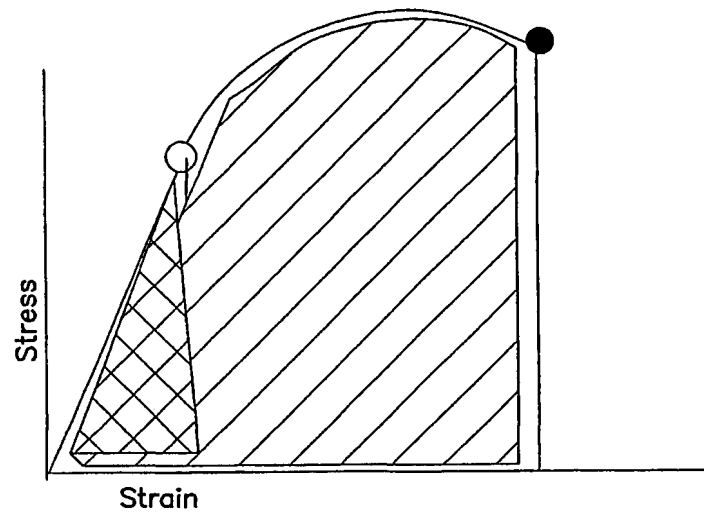


FIG. 18

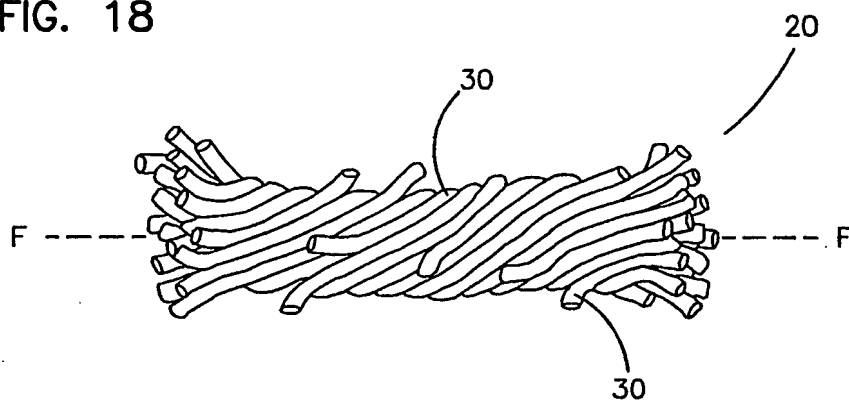


FIG. 19

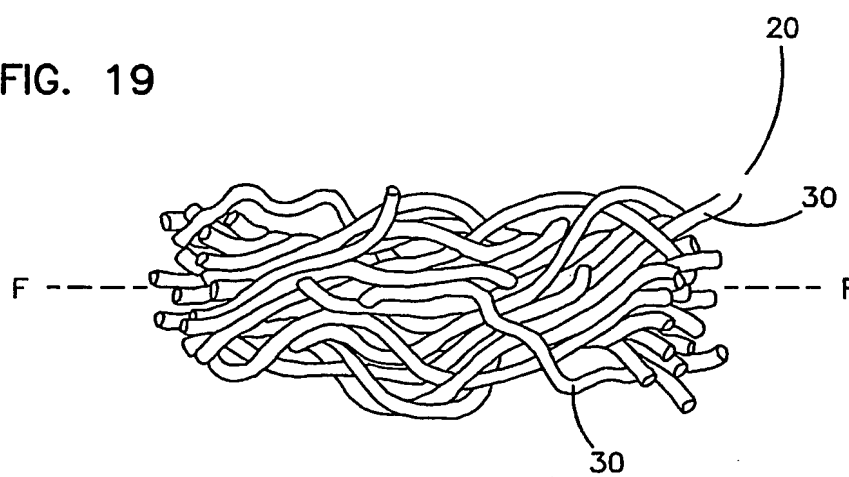


FIG. 20

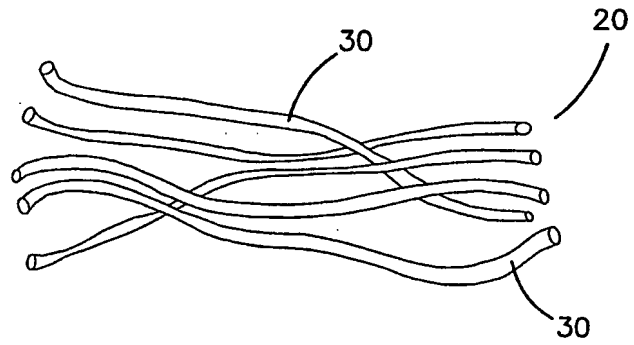
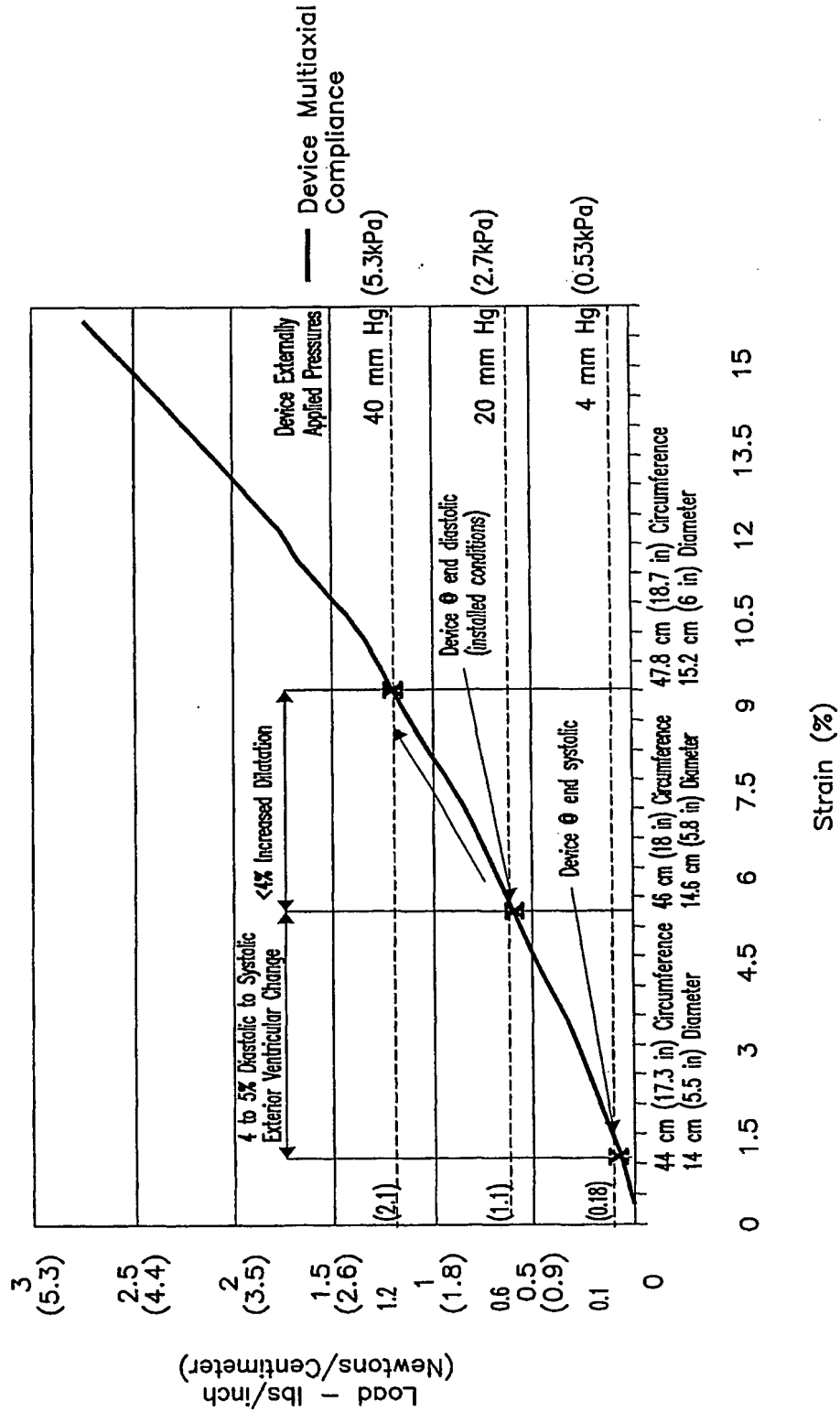


FIG. 21

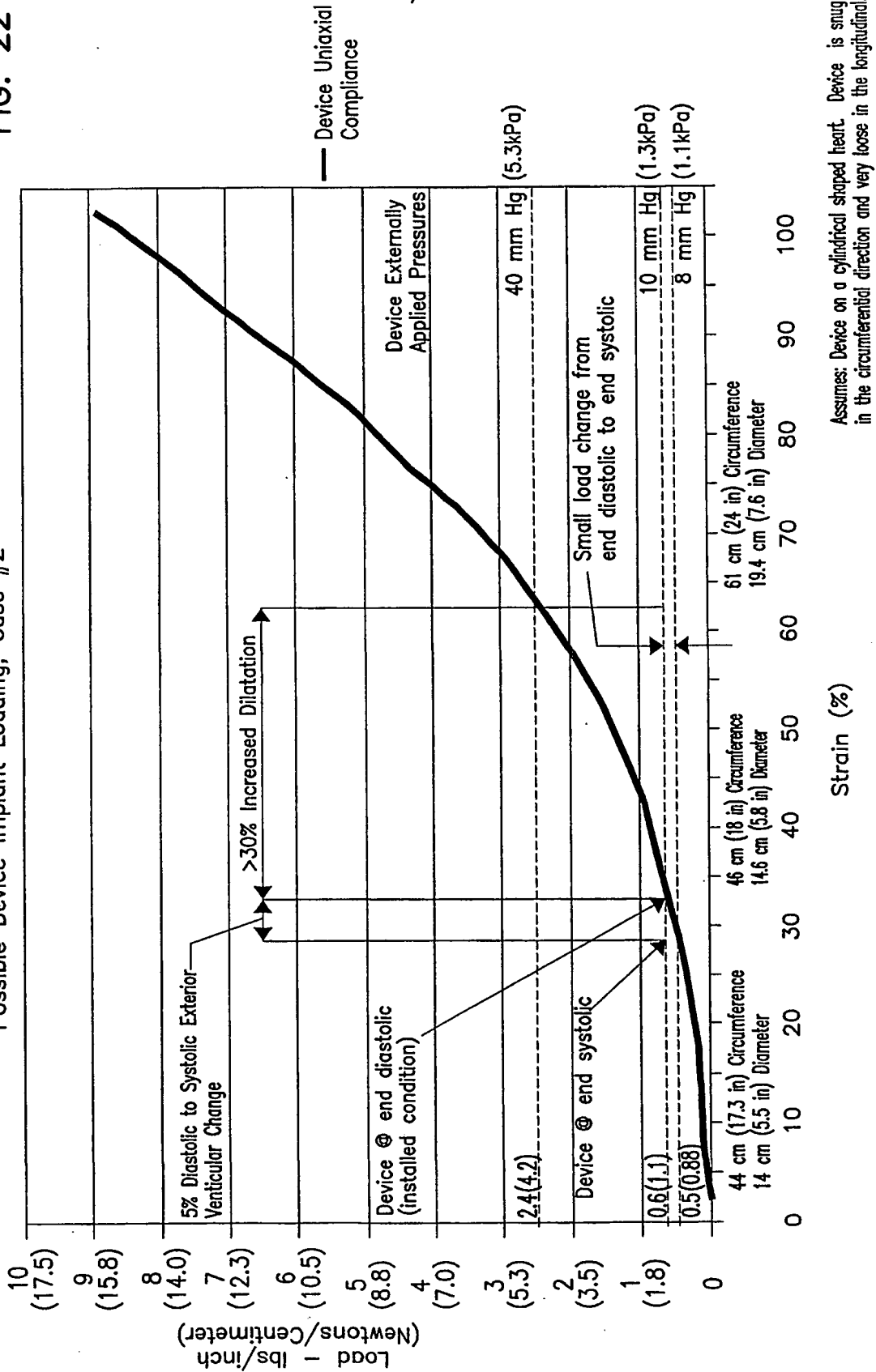
Possible Device Implant Loading, Case #1



Assumes: Device on a spherical shaped heart.

FIG. 22

Possible Device Implant Loading, Case #2



Assumes: Device on a cylindrical shaped heart. Device is snug in the circumferential direction and very loose in the longitudinal.

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(54) Title: **CARDIAC DISEASE TREATMENT AND DEVICE**

(57) Abstract: A device for treating cardiac disease of a heart having an upper portion and a lower portion divided by an A-V groove, the device including a jacket adapted to be secured to the heart, and a non-adherent material in association with the jacket. The jacket is fabricated from a flexible material defining a volume between an upper and a lower end, the jacket being adapted to be adjusted on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain expansion of the heart beyond the maximum adjusted volume during diastole and permit substantially unimpeded contraction of the heart during systole. As a result of the flexible material, the jacket allows unimpeded diastolic filling of the heart. Also described is a method for treating cardiac disease including surgically accessing the heart, applying the treatment device of the invention, securing the treatment device to the heart, and surgically closing access to the heart while leaving the treatment device on the heart.



## CARDIAC DISEASE TREATMENT AND DEVICE

This application is being filed as a PCT application by ACORN  
CARDIOVASCULAR, INC., a United States national and resident, designating all  
5 countries except US.

### FIELD OF THE INVENTION

The present invention relates a device and method for treatment of cardiac  
disease and related cardiac complications. In particular, the present invention relates  
10 to a device for treating cardiac disease that includes a jacket that is adapted to be  
secured to the heart, and non-adherent material provided in association with the  
jacket.

### BACKGROUND OF THE INVENTION

15 Chronic or congestive heart disease is a progressive and debilitating illness.  
The disease is characterized by a progressive enlargement of the heart. Often, heart  
failure develops as a consequence of coronary atherosclerosis and myocardial  
infarction. After an infarction, the irreversibly injured myocardium is gradually  
replaced with fibrous scar tissue, since myocytes have limited ability to proliferate,  
20 and lost myocytes cannot regenerate. As myocytes are replaced with fibroblasts and  
collagen, changes in the mechanics of the heart lead to progressive onset of  
congestive heart failure.

As the heart enlarges, the heart is performing an increasing amount of work  
in order to pump blood with each heart beat. In time, the heart becomes so enlarged  
25 the heart cannot adequately supply blood. An afflicted patient is fatigued, unable to  
perform even simple exerting tasks and experiences pain and discomfort. Further, as  
the heart enlarges, the internal heart valves cannot adequately close. This impairs  
the function of the valves and further reduces the heart's ability to supply blood.

Causes of congestive heart disease are not fully known. In certain instances,  
30 congestive heart disease may result from viral infections. In such cases, the heart  
may enlarge to such an extent that the adverse consequences of heart enlargement  
continue after the viral infection has passed and the disease continues its

progressively debilitating course.

Patients suffering from congestive heart disease are commonly grouped into four classes (i.e., NYHA Classes I, II, III and IV). In the early stages (e.g., Classes I and II), drug therapy is the commonly proscribed treatment. Drug therapy treats the symptoms of the disease and may slow the progression of the disease. Importantly, there is no cure for congestive heart disease. Even with drug therapy, the disease will progress. Further, the drugs may have adverse side effects, particularly when they are administered through the bloodstream.

Presently, the only permanent treatment for congestive heart disease is heart transplant. To qualify, a patient must be in the later stage of the disease (e.g., Classes III and IV with Class IV patients given priority for transplant). Such patients are extremely sick individuals. Class III patients have marked physical activity limitations and Class IV patients are symptomatic even at rest.

Due to the absence of effective intermediate treatment between drug therapy and heart transplant, Class III and IV patients will have suffered terribly before qualifying for heart transplant. Further, after such suffering, the available treatment is unsatisfactory. Heart transplant procedures are very risky, extremely invasive and expensive and only shortly extend a patient's life. For example, prior to transplant, a Class IV patient may have a life expectancy of 6 months to one-year. Heart transplant may improve the expectancy to about five years.

Unfortunately, not enough hearts are available for transplant to meet the needs of congestive heart disease patients. In the United States, in excess of 35,000 transplant candidates compete for only about 2,000 transplants per year. A transplant waiting list is about 8 – 12 months long on average and frequently a patient may have to wait about 1 – 2 years for a donor heart. While the availability of donor hearts has historically increased, the rate of increase is slowing dramatically. Even if the risks and expense of heart transplant could be tolerated, this treatment option is becoming increasingly unavailable. Further, many patient's do not qualify for heart transplant for failure to meet any one of a number of qualifying criteria.

Congestive heart failure has an enormous societal impact. In the United States alone, about five million people suffer from the disease (Classes I through IV).

combined). Alarmingly, congestive heart failure is one of the most rapidly accelerating diseases (about 400,000 new patients in the United States each year). Economic costs of the disease have been estimated at \$38 billion annually.

Not surprising, substantial effort has been made to find alternative treatments for congestive heart disease and related complications. One alternative treatment is described in commonly assigned U.S. Patent No. 5,702,343 to Alferness dated December 30, 1997 teaches a jacket to constrain cardiac expansion during diastole. The present invention pertains to improvements to the invention disclosed in the '343 patent.

10

### SUMMARY OF THE INVENTION

The present invention provides a device and method for treating cardiac disease and related cardiac complications. According to the invention, the device comprises a jacket that is adapted to be secured to the heart, and a non-adherent material in association with the jacket. Preferably, the non-adherent material prevents unwanted fibrosis or adhesion to the heart as a result of the presence of the jacket on the heart surface. The non-adherent material can be formed as an integral part of the jacket, or can be provided as a separate element of the overall device. Positioning of the non-adherent material can be controlled to reduce the risk of fibrosis or other adverse effects on the surface of the heart or surrounding organs. Preferably, the non-adherent material is located within or on the jacket such that it overlies areas of the heart surface containing major blood vessels, to facilitate access to those blood vessels, if the need should arise. The non-adherent material also facilitates removal of the jacket, if such removal becomes desirable or necessary. In one embodiment, the non-adherent material comprises a coating on the jacket. Alternatively, the non-adherent material comprises a separable element of the device and is provided in connection with the jacket.

In one embodiment, a device for treating cardiac disease comprises a jacket of flexible material that is secured to the heart and conforms to an external geometry of the heart, and a non-adherent material to prevent unwanted fibrosis on the surface of the heart. Preferably, the jacket is adapted to be adjusted on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted

volume for the jacket to constrain expansion of the heart beyond the maximum adjusted volume during diastole and permit substantially unimpeded contraction of the heart during systole. In one aspect, the non-adherent material is adapted to cover only a specific area, or the entire surface area, of the heart.

- 5           In another embodiment, methods for treating cardiac disease and related cardiac complications are described, the method comprising surgically accessing the heart; applying a treatment device on the heart, the device comprising a jacket of flexible material that is secured to the heart and conforms to an external geometry of the heart, and a non-adherent material in association with the jacket; securing the  
10 treatment device to the heart; and surgically closing access to the heart while leaving the treatment device on the heart.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

- 15           Fig. 1 is a schematic cross-sectional view of a normal, healthy human heart shown during systole;  
            Fig. 1A is the view of Fig. 1 showing the heart during diastole;  
            Fig. 1B is a view of a left ventricle of a healthy heart as viewed from a septum and showing a mitral valve;  
20           Fig. 2 is a schematic cross-sectional view of a diseased human heart shown during systole;  
            Fig. 2A is the view of Fig. 2 showing the heart during diastole;  
            Fig. 2B is the view of Fig. 1B showing a diseased heart;  
            Fig. 3 is a perspective view of a first embodiment of a cardiac constraint  
25 device according to the present invention;  
            Fig. 3A is a side elevation view of a diseased heart in diastole with the device of Fig. 3 in place;  
            Fig. 4 is a perspective view of a second embodiment of a cardiac constraint device according to the present invention;  
30           Fig. 4A is a side elevation view of a diseased heart in diastole with the device of Fig. 4 in place;  
            Fig. 5 is a cross-sectional view of a device of the present invention overlying

a myocardium and with the material of the device gathered for a snug fit;

Fig. 6 is an enlarged view of a knit construction of the device of the present invention in a rest state;

Fig. 7 is a schematic view of the material of Fig. 6; and

5 Fig. 8 is a perspective view of an embodiment of a cardiac reinforcement device according to the invention, including non-adherent biocompatible material placed between the jacket and the myocardium; and

Fig. 9 is a perspective view of an embodiment of a cardiac reinforcement device according to the invention, including non-adherent biocompatible material in  
10 the form of ribs in association with the jacket.

### **DETAILED DESCRIPTION**

The present invention provides devices and methods for treatment of cardiac conditions such as cardiomyopathy, valvular insufficiency, arrhythmias, and other  
15 cardiac complications. Generally, the invention is directed to a jacket that is secured to the heart and constrains expansion of the heart during diastole to a predetermined limit, and a delivery source for the delivery of a therapeutic agent to the surface of the heart.

The present invention provides advantages over known methods of treatment  
20 for cardiac disorders. Many known methods of drug treatment involve delivering the drugs to the site of action through the bloodstream. The amount of time required for these drugs to have the desired effect, and how long their effects last often depend upon several factors, including how quickly the drugs get into the bloodstream, how much of them gets into the bloodstream, how quickly they leave  
25 the bloodstream, how efficiently they are broken down (metabolized) by the liver, and how quickly they are eliminated by the kidneys and intestines. A drug may move slowly from the bloodstream into the body's tissues. Moreover, drugs penetrate different tissues at different speeds, depending upon their ability to cross membranes. In general, fat-soluble drugs can cross cell membranes more quickly  
30 than water-soluble drugs.

Intravenous administration of a drug may present adverse side effects when the systemic level of a drug exceeds a tolerable limit. Distribution of a drug may be

further complicated when the drug is administered into the bloodstream. Once absorbed, most drugs do not spread out evenly through the body. Some drugs tend to stay within the watery tissues of the blood and muscles, while others concentrate in specific tissues such as the thyroid gland, liver, and kidneys. Additionally, some  
5 drugs bind tightly to blood proteins, leaving the bloodstream very slowly, while others escape from the bloodstream quickly into other tissues. Some tissues build up such high levels of a drug that they serve as reservoirs of extra drug, thereby prolonging the drug's distribution. In fact, some drugs, such as those that accumulate in fatty tissues, leave these tissues slowly and consequently circulate in  
10 the bloodstream for some days after a person has stopped taking the drug.

In contrast, localized, targeted delivery of the drug can avoid undesirable systemic effects by eliminating circulation of the drug in areas of the body other than the target tissue.

It would be beneficial to be able to treat congestive heart disease or other related  
15 cardiac disorder with a drug while avoiding undesirable systemic effects such as drug-associated systemic toxic effects.

The present invention provides a combination of such advantages as controllability of therapeutic agent delivery (including duration of exposure to the agent, dosage, and size of the target area to be exposed to the agent), and contact  
20 between the therapeutic agent and the target surface that is intimate, long-term, and non-shifting. The present invention can target delivery of the therapeutic agent to a specific target area on or around the heart. If desired, the entire surface of the heart can be treated with the agent, or one or more specific areas of the heart can be treated. The ability to target the therapeutic agent as desired avoids adverse systemic  
25 effects of therapeutic agents.

The present invention maintains a controlled release of the therapeutic agent after implantation of the device. According to the present invention, the delivery source for delivery of a therapeutic agent to the surface of the heart is provided in non-shifting contact with the heart surface, allowing sustained treatment of a defined  
30 area of the heart. The present invention also provides a flexible device for delivery of the therapeutic agent, such that the device maintains intimate contact with the heart during delivery of the agent. This intimate, non-shifting contact with the heart

achieves local delivery of a therapeutic agent that might otherwise be impossible or at least difficult to deliver as a result of such factors as poor blood flow to the target surface, for example, as a result of ischemia. Because the present invention delivers the therapeutic agent directly to a localized target surface, lower amounts, but  
5 potentially higher localized concentrations, of the therapeutic agent can be delivered.

The invention is not limited to treatment of the heart. The device and method can be used to treat tissues surrounding the heart or other tissues of the body, as desired. The invention thus provides controlled release of a therapeutic agent to tissues of the body.

10 In one preferred embodiment, the mechanical energy of the heart drives drug delivery. In this embodiment, for example, the pressure of the heart against the jacket of the device controls release of the therapeutic agent from the delivery source of the device. In another preferred embodiment, the present invention can expose the target tissue to a combination of agents, when treatment with more than one type  
15 of agent is desired. For example, one or more anti-arrhythmic drugs and one or more desired antibiotics can be provided in connection with the device, when the physician determines that both the rhythm of the heart and potential infections are to be controlled.

With initial reference to Figs. 1 and 1A, a normal, healthy human heart H' is  
20 schematically shown in cross-section and will now be described in order to facilitate an understanding of the present invention. In Fig. 1, the heart H' is shown during systole (i.e., high left ventricular pressure). In Fig. 1A, the heart H' is shown during diastole (i.e., low left ventricular pressure).

The heart H' is a muscle having an outer wall or myocardium MYO' and an  
25 internal wall or septum S'. The myocardium MYO' and septum S' define four internal heart chambers including a right atrium RA', a left atrium LA', a right ventricle RV' and a left ventricle LV'. The heart H' has a length measured along a longitudinal axis AA' - BB' from an upper end or base B' to a lower end or apex A'.

The right and left atria RA', LA' reside in an upper portion UP' of the heart H'  
30 adjacent the base B'. The right and left ventricles RV', LV' reside in a lower portion LP' of the heart H' adjacent the apex A'. The ventricles RV', LV' terminate at ventricular lower extremities LE' adjacent the apex A' and spaced therefrom by the

thickness of the myocardium MYO'.

Due to the compound curves of the upper and lower portions UP', LP', the upper and lower portions UP', LP' meet at a circumferential groove commonly referred to as the A-V groove AVG'. Extending away from the upper portion UP' are a plurality of major blood vessels communicating with the chambers RA', RV', LA', LV'. For ease of illustration, only the superior vena cava SVC' and a left pulmonary vein LPV' are shown as being representative.

The heart H' contains valves to regulate blood flow between the chambers RA', RV', LA', LV' and between the chambers and the major vessels (e.g., the superior vena cava SVC' and a left pulmonary vein LPV'). For ease of illustration, not all of such valves are shown. Instead, only the tricuspid valve TV' between the right atrium RA' and right ventricle RV' and the mitral valve MV' between the left atrium LA' and left ventricle LV' are shown as being representative.

The valves are secured, in part, to the myocardium MYO' in a region of the lower portion LP' adjacent the A-V groove AVG' and referred to as the valvular annulus VA'. The valves TV' and MV' open and close through the beating cycle of the heart H.

Figs. 1 and 1A show a normal, healthy heart H' during systole and diastole, respectively. During systole (Fig. 1), the myocardium MYO' is contracting and the heart assumes a shape including a generally conical lower portion LP'. During diastole (Fig. 1A), the heart H' is expanding and the conical shape of the lower portion LP' bulges radially outwardly (relative to axis AA' – BB').

The motion of the heart H' and the variation in the shape of the heart H' during contraction and expansion is complex. The amount of motion varies considerably throughout the heart H'. The motion includes a component which is parallel to the axis AA' – BB' (conveniently referred to as longitudinal expansion or contraction). The motion also includes a component perpendicular to the axis AA'-BB' (conveniently referred to as circumferential expansion or contraction).

Having described a healthy heart H' during systole (Fig. 1) and diastole (Fig. 1A), comparison can now be made with a heart deformed by congestive heart disease. Such a heart H is shown in systole in Fig. 2 and in diastole in Fig. 2A. All elements of diseased heart H are labeled identically with similar elements of healthy



heart H' except only for the omission of the apostrophe in order to distinguish diseased heart H from healthy heart H'.

Comparing Figs. 1 and 2 (showing hearts H' and H during systole), the lower portion LP of the diseased heart H has lost the tapered conical shape of the lower  
5 portion LP' of the healthy heart H'. Instead, the lower portion LP of the diseased heart H bulges outwardly between the apex A and the A-V groove AVG. So deformed, the diseased heart H during systole (Fig. 2) resembles the healthy heart H' during diastole (Fig. 1A). During diastole (Fig. 2A), the deformation is even more extreme.

10 As a diseased heart H enlarges from the representation of Figs. 1 and 1A to that of Figs. 2 and 2A, the heart H becomes a progressively inefficient pump. Therefore, the heart H requires more energy, with greater oxygen demand, to pump the same amount of blood. Continued progression of the disease results in the heart H being unable to supply adequate blood to the patient's body and the patient  
15 exhibits symptomatic insufficiency.

For ease of illustration, the progression of congestive heart disease has been illustrated and described with reference to a progressive enlargement of the lower portion LP of the heart H. While such enlargement of the lower portion LP is most common and troublesome, enlargement of the upper portion UP may also occur.

20 In addition to cardiac insufficiency, the enlargement of the heart H can lead to valvular disorders. As the circumference of the valvular annulus VA increases, the leaflets of the valves TV and MV may spread apart. After a certain amount of enlargement, the spreading may be so severe the leaflets cannot completely close (as illustrated by the mitral valve MV in Fig. 2A). Incomplete closure results in  
25 valvular regurgitation contributing to an additional degradation in cardiac performance. While circumferential enlargement of the valvular annulus VA may contribute to valvular dysfunction as described, the separation of the valve leaflets is most commonly attributed to deformation of the geometry of the heart H. This is best described with reference to Figs. 1B and 2B.

30 Figs. 1B and 2B show a healthy and diseased heart, respectively, left ventricle LV', LV during systole as viewed from the septum (not shown in Figs. 1B and 2B). In a healthy heart H', the leaflets MVL' of the mitral valve MV' are urged

closed by left ventricular pressure. The papillary muscles PM', PM are connected to the heart wall MYO', MYO, near the lower ventricular extremities LE', LE. The papillary muscles PM', PM pull on the leaflets MVL', MVL via connecting chordae tendineae CT', CT. Pull of the leaflets by the papillary muscles functions to prevent valve leakage in the normal heart by holding the valve leaflets in a closed position during systole. In the significantly diseased heart H, the leaflets of the mitral valve may not close sufficiently to prevent regurgitation of blood from the ventricle LV to the atrium during systole.

As shown in Fig. 1B, the geometry of the healthy heart H' is such that the myocardium MYO', papillary muscles PM' and chordae tendineae CT' cooperate to permit the mitral valve MV' to fully close. However, when the myocardium MYO bulges outwardly in the diseased heart H (Fig. 2B), the bulging results in displacement of the papillary muscles PM. This displacement acts to pull the leaflets MVL to a displaced position such that the mitral valve cannot fully close.

Having described the characteristics and problems of congestive heart disease, the treatment method and apparatus of the present invention will now be described.

The device of the present invention comprises a jacket adapted to be secured to the heart and a delivery source for delivery of one or more therapeutic agents to the heart. In general, a jacket of the invention is configured to surround the myocardium MYO. As used herein, "surround" means that the jacket provides reduced expansion of the heart wall at end diastole by applying constraining surfaces at least at diametrically opposing aspects of the heart. In some preferred embodiments disclosed herein, the diametrically opposed surfaces are interconnected, for example, by a continuous material that can substantially encircle the external surface of the heart. The jacket is also preferably fabricated from a flexible material to allow unrestricted filling of the heart during diastole.

With reference now to Figs. 3, 3A, 4 and 4A, the device of the present invention is shown as a jacket 10 of flexible, biologically compatible material. As used herein, "biologically compatible material" means material that is not biologically adverse such that the material will not cause adverse effects to

surrounding tissues, such as rejection, infection, inflammation, and the like. Such material can be a biostable material such as a biostable polymer, or a biodegradable material, as discussed in more detail below.

The jacket 10 is an enclosed knit material having upper and lower ends 12, 14. The jacket 10, 10' defines an internal volume 16, 16' which is completely enclosed but for the open ends 12, 12' and 14'. In the embodiment of Fig. 3, lower end 14 is closed. In the embodiment of Fig. 4, lower end 14' is open. In both embodiments, upper ends 12, 12' are open. Alternatively, upper ends 12, 12' can be closed while allowing the SVC, LVC and other blood vessels to pass through the jacket material. Throughout this description, the embodiment of Fig. 3 will be discussed. Elements in common between the embodiments of Figs. 3 and 4 are numbered identically with the addition of an apostrophe to distinguish the second embodiment and such elements need not be separately discussed.

The jacket 10 is dimensioned with respect to a heart H to be treated. Specifically, the jacket 10 is sized for the heart H to be constrained within the volume 16. The jacket 10 can be slipped around the heart H. The jacket 10 has a length L between the upper and lower ends 12, 14 sufficient for the jacket 10 to constrain the lower portion LP. The upper end 12 of the jacket 10 extends at least to the valvular annulus VA and further extends to the lower portion LP to constrain at least the lower ventricular extremities LE.

The jacket of the invention can be provided in any suitable size and shape for application to the heart. In one embodiment, for example, the jacket 10 is provided in a conical shape. As used herein, "conical" refers to a shape of the jacket wherein the diameter of the jacket decreases from the upper end 12, 12' towards the lower end 14, 14', to approximate the ellipsoid shape of the heart. In one embodiment, the size of the jacket 10 is predetermined, such that the jacket is fabricated in a conical shape prior to application to the heart. Alternatively, the shape of the jacket is adjusted at the time of placement of the device on the heart.

Since enlargement of the lower portion LP is most troublesome, in a preferred embodiment, the jacket 10 is sized so that the upper end 12 can reside in the A-V groove AVG. Where it is desired to constrain enlargement of the upper portion UP, the jacket 10 may be extended to cover the upper portion UP.

Sizing the jacket 10 for the upper end 12 to terminate at the A-V groove AVG may be desirable for a number of reasons. First, the groove AVG is a readily identifiable anatomical feature to assist a surgeon in placing the jacket 10. By placing the upper end 12 in the A-V groove AVG, the surgeon is assured the jacket 10 will provide sufficient constraint at the valvular annulus VA. The A-V groove AVG and the major vessels act as natural stops for placement of the jacket 10 while assuring coverage of the valvular annulus VA. Using such features as natural stops is particularly beneficial in minimally invasive surgeries where a surgeon's vision may be obscured or limited.

When the parietal pericardium is opened, the lower portion LP is free of obstructions for applying the jacket 10 over the apex A. If, however, the parietal pericardium is intact, the diaphragmatic attachment to the parietal pericardium inhibits application of the jacket over the apex A of the heart. In this situation, the jacket can be opened along a line extending from the upper end 12' to the lower end 14' of jacket 10'. The jacket can then be applied around the pericardial surface of the heart and the opposing edges of the opened line secured together after being placed on the heart. Systems for securing the opposing edges are disclosed in, for example, U.S. Patent No. 5,702,343, the entire disclosure of which is incorporated herein by reference.

In the embodiment of Figs. 3 and 3A, the lower end 14 is closed and the length L is sized for the apex A of the heart H to be received within the lower end 14 when the upper end 12 is placed at the A-V groove AVG. In the embodiment of Figs. 4 and 4A, the lower end 14' is open and the length L' is sized for the apex A of the heart H to protrude beyond the lower end 14' when the upper end 12' is placed at the A-V groove AVG. The length L' is sized so that the lower end 14' extends beyond the lower ventricular extremities LE such that in both of jackets 10, 10', the myocardium MYO surrounding the ventricles RV, LV is in direct opposition to material of the jacket 10, 10'. Such placement is desirable for the jacket 10, 10' to present a constraint against enlargement of the ventricular walls of the heart H.

After the jacket 10 is positioned on the heart H as described above, the jacket 10 is secured to the heart. Preferably, the jacket 10 is secured to the heart H through sutures or other suitable surgical attachment methods. The jacket 10 is sutured to

the heart H at suture locations S circumferentially spaced along the upper end 12. While a surgeon may elect to add additional suture locations to prevent shifting of the jacket 10 after placement, the number of such locations S is preferably limited so that the jacket 10 does not restrict contraction of the heart H during systole.

5 In another embodiment, the jacket is secured to the heart using a suitable bioadhesive. The bioadhesive can be used in connection with a jacket alone, or in combination with one or more therapeutic agents and/or a nonadherent material. As used herein, a "bioadhesive" means a material that adheres an element to a biological tissue, or two biological tissues to each other. Preferably, the bioadhesive  
10 is fabricated from a material that is biologically compatible and allows secure attachment to a tissue. According to the present invention, preferred bioadhesives attach the jacket 10 to the heart in a sufficient non-shifting manner and for a sufficient amount of time to allow the desired effects. The bioadhesive preferably secures the jacket sufficiently to avoid dislocation of the jacket as a result of the  
15 heart's natural movement. Preferred bioadhesives are thus somewhat flexible to accommodate movement of the heart or surrounding tissue.

Preferably, bioadhesives used in accordance with the invention do not cause undesired adverse effects, such as irritation, inflammation, infection, and the like, of tissues of the heart and/or in proximity thereto. Preferably, when the jacket is used  
20 in connection with a bioadhesive, suitable bioadhesives do not interfere with penetration of a therapeutic agent from the device into the myocardium. In one embodiment, areas of the device that include one or more bioadhesives are separate from areas that include one or more therapeutic agents. Alternatively, areas of the device that include one or more bioadhesives overlap areas that include one or more  
25 therapeutic agents. In this alternative embodiment, the bioadhesive is preferably permeable to the therapeutic agent, so that the bioadhesive does not interfere with release of the therapeutic agent to the surface of the heart. In yet another embodiment, the bioadhesive itself includes one or more therapeutic agents.

Preferred bioadhesives are fabricated from such materials as polyethylene  
30 glycol, fibrin, cyanoacrylate, or material comprising a combination of bovine serum albumin (BSA) and glutaraldehyde. Suitable polyethylene glycol-based materials are provided by Focal, Inc., under the product name Focal Seal™, and Cohesion

Technologies, Inc. under the product name CoSeal™. Examples of fibrin-based materials are provided by Haemacure Corporation under the product name Hemaseel™. Suitable material based in combining bovine serum albumin and gluteraldehyde are provided by Cryolife International, Inc.. Examples of  
5 cyanoacrylate-based materials are provided by Johnson & Johnson under product name Dermabond™. Other suitable bioadhesives known in the art could be substituted for the above materials, given the description herein.

To permit the jacket 10 to be easily placed on the heart H, the volume and shape of the jacket 10 are larger than the lower portion LP during diastole. So sized,  
10 the jacket 10 may be easily slipped around the heart H. Once placed, the jacket's volume and shape are adjusted for the jacket 10 to snugly conform to the external geometry of the heart H during diastole. Such sizing is easily accomplished due to the knit construction of the jacket 10. For example, excess material of the jacket 10 can be gathered and sutured S" (Fig. 5) to reduce the volume of the jacket 10 and  
15 conform the jacket 10 to the shape of the heart H during diastole. Such shape represents a maximum adjusted volume. The jacket 10 constrains enlargement of the heart H beyond the maximum adjusted volume while preventing restricted contraction of the heart H during systole. Preferably, the flexible material of the jacket allows unrestricted filling of the heart during diastole. As an alternative to  
20 gathering of Fig. 5, the jacket 10 can be provided with other ways of adjusting volume. For example, as disclosed in U.S. Patent No. 5,702,343, the jacket can be provided with a slot. The edges of the slot can be drawn together to reduce the volume of the jacket.

The volume of the jacket can be adjusted prior to, during, or after application  
25 of the device to the heart. In one embodiment, the heart is treated with a therapeutic agent, such as a drug, to decrease the size of the heart prior to application of the jacket. In this embodiment, the therapeutic agent acts to reduce the overall size of the heart prior to surgery, and the jacket is thereafter applied to the reduced heart. In another embodiment, the size of the heart is reduced by placement of the device on  
30 the heart, and sizing of the device to urge the heart to a reduced size. More preferably, the heart size can be reduced at the time of jacket placement through drugs, for example dobutamine, dopamine or epinephrine or any other positive

inotropic agents. Alternatively, surgical procedure can be used to reduce the heart size. The jacket of the present invention is then snugly placed on the reduced sized heart and prevents or reduces enlargement beyond the reduced size.

The jacket 10 is adjusted to a snug fit on the heart H during diastole. Care is taken to avoid tightening the jacket 10 too much such that cardiac function is impaired. During diastole, the left ventricle LV fills with blood. If the jacket 10 is too tight, the left ventricle LV cannot adequately expand and left ventricular pressure will rise. During the fitting of the jacket 10, the surgeon can monitor left ventricular pressure. For example, a well-known technique for monitoring so-called pulmonary wedge pressure uses a catheter placed in the pulmonary artery. The wedge pressure provides an indication of filling pressure in the left atrium LA and left ventricle LV. While minor increases in pressure (e.g., 2 – 3 mm Hg) can be tolerated, the jacket 10 is snugly fit on the heart H but not so tight as to cause a significant increase in left ventricular pressure during diastole.

The jacket 10 is constructed from a knit, biocompatible material. The knit 18 is illustrated in Fig. 6. Preferably, the knit is a so-called "Atlas knit" well known in the fabric industry. The Atlas knit is described in Paling, Warp Knitting Technology, p. 111, Columbine Press (Publishers) Ltd., Buxton, Great Britain (1970).

The Atlas knit is a knit of fibers 20 having directional expansion properties. More specifically, the knit 18, although formed of generally inelastic fibers 20, permits a construction of a flexible fabric at least slightly expandable beyond a rest state. Fig. 6 illustrates the knit 18 in a rest state. The fibers 20 of the fabric 18 are woven into two sets of fiber strands 21a, 21b having longitudinal axes  $X_a$  and  $X_b$ . The strands 21a, 21b are interwoven to form the fabric 18 with strands 21a generally parallel and spaced-apart and with strands 21b generally parallel and spaced-apart.

For ease of illustration, fabric 18 is schematically shown in Fig. 7 with the axis of the strands 21a, 21b only being shown. The strands 21a, 21b are interwoven with the axes  $X_a$  and  $X_b$  defining a diamond-shaped open cell 23 having diagonal axes  $A_m$ . In a preferred embodiment, the axes  $A_m$  are 5 mm in length when the fabric 18 is at rest and not stretched. The fabric 18 can stretch in response to a force. For any given force, the fabric 18 stretches most when the force is applied parallel to the

diagonal axes  $A_m$ . The fabric 18 stretches least when the force is applied parallel to the strand axes  $X_a$  and  $X_b$ . The jacket 10 is constructed for the material of the knit to be directionally aligned for a diagonal axis  $A_m$  to be parallel to the heart's longitudinal axis AA-BB.

5           While the jacket 10 is expandable due to the above described knit pattern, the fibers 20 of the knit 18 are preferably non-expandable. While all materials expand at least a small amount, the fibers 20 are preferably formed of a material with a low modulus of elasticity. In response to the low pressures in the heart H during diastole, the fibers 20 are essentially non-elastic. In a preferred embodiment, the  
10       fibers are 70 Denier polyester. While polyester is presently preferred, other suitable materials include polytetrafluoroethylene (PTFE), polypropylene, stainless steel, and the like. Alternatively, the fibers of the jacket are fabricated from a suitable biodegradable material or blends thereof, as described herein.

          The knit material has numerous advantages. Such a material is flexible to  
15       permit unrestricted movement of the heart H (other than the desired constraint on cardiac dilation). The material is open, defining a plurality of interstitial spaces for fluid permeability as well as minimizing the amount of surface area of direct contact between the heart H and the material of the jacket 10 (thereby minimizing areas of irritation or abrasion) to minimize fibrosis and scar tissue.

20           The open areas of the knit construction also allow for electrical connection between the heart and surrounding tissue for passage of electrical current to and from the heart. For example, although the knit material is an electrical insulator, the open knit construction is sufficiently electrically permeable to permit the use of trans-chest defibrillation of the heart. Also, the open, flexible construction permits  
25       passage of electrical elements (e.g., pacer leads) through the jacket. Additionally, the open construction permits other procedures, e.g., coronary bypass, to be performed without removal of the jacket.

          In one preferred embodiment, the interstitial spaces of the knit construction contain the therapeutic agent of the present invention. For example, in one  
30       embodiment, the interstitial spaces are filled with a biodegradable space fill material comprising a biologically compatible and/or biodegradable polymer matrix containing the therapeutic agent, as discussed in more detail below.



A large open area for cells 23 is desirable to minimize the amount of surface area of the heart H in contact with the material of the jacket 10 (thereby reducing fibrosis). However, if the cell area 23 is too large, localized aneurysm can form. Also, a strand 21a, 21b can overlay a coronary vessel with sufficient force to partially block the vessel. A smaller cell size increases the number of strands thereby decreasing the restricting force per strand. In a preferred embodiment, the cell area CA of cells in a particular row directly correlates with a cross-sectional circumferential dimension of the heart that the row of cells surrounds relative to other cross-sectional circumferential dimensions. That is, the greater the cross-sectional circumferential dimension, the greater the area of the cells in the row of cells directly overlying that cross-sectional circumferential dimension. By "correlating" cell area with cross-sectional circumferential dimension of the heart, the cell area is determined as a function of the cross-sectional circumferential dimension of the heart. The cell area is determined so that when the weave material is applied to the heart or is shaped into a jacket and applied to the heart, each cell can widen sufficiently to provide desirable cardiac constraint. Thus, the cell area will be smaller for cells in a row applied over a region of the heart that has a smaller cross-sectional circumferential dimension than the cell area of cells in a row applied over a region of the heart having a larger cross-sectional circumferential dimension. The appropriate maximum cell area may be, for example, 1 to 100 mm<sup>2</sup>, typically 3 to 9 mm<sup>2</sup>. The maximum cell area is the area of a cell 23 after the material of the jacket 10 is fully stretched and adjusted to the maximum adjusted volume on the heart H as previously described.

The fabric 18 is preferably tear and run resistant. In the event of a material defect or inadvertent tear, such a defect or tear is restricted from propagation by reason of the knit construction.

In an alternative embodiment, the jacket is fabricated from an elastic material. A biologically compatible material suitable for a device of the invention generally has a lower compliance than the heart wall. Even though the biologically compatible material is less compliant than the heart wall, some limited expansion of an elastic biologically compatible material can occur during cardiac filling. Suitable elastic materials for jacket fabrication include, for example, polyurethane, silicone,

and the like.

Regardless if the biologically compatible material is elastic or non-elastic, advantageous to a device according to the present invention is cardiac reinforcement which is provided during diastole. Moreover, a device as disclosed herein does not  
5 provide cardiac assistance through active pumping of the heart.

A device and method to treat cardiac disease have been disclosed in U.S. Patent No. 5,702,343 (commonly assigned to the assignee of the present invention, and the disclosure of which is incorporated herein by reference). The jacket 10  
10 constrains further undesirable enlargement of the heart while not impeding other motion of the heart H. With the benefits of the present teachings, numerous modifications are possible. For example, the jacket 10 need not be directly applied to the epicardium (i.e., outer surface of the myocardium) but could be placed over the parietal pericardium. Further, an anti-fibrosis lining (such as a PTFE, polyethylene glycol, polyethylene oxide, or other polymer coating on the fibers of  
15 the knit) could be used with the jacket 10, for example, between the heart and the jacket, or applied on the outer surface of the jacket (away from the heart). Alternatively, the fibers 20 can be coated with PTFE.

In one embodiment, a non-adherent material is provided in connection with the jacket 10 of the invention, to prevent unwanted fibrosis as a result of the  
20 presence of the jacket on the surface of the heart. As used herein, "non-adherent material" means a material that is biocompatible and does not adhere to surfaces of organs, such as the epicardial surface of the heart. The material can be preformed in a manner similar to the jacket of the invention, as described above. In one embodiment, the non-adherent material is fabricated as part of the jacket of the  
25 invention. Alternatively, the non-adherent material is fabricated as a separate element of the invention, and is positioned between the jacket of the invention and the epicardial surface of the heart. The non-adherent material facilitates removal of the jacket, which can become difficult when the jacket has been in place on the heart for a long period of time.

30 In another embodiment, the non-adherent material is placed on the outer surface of the jacket; that is, the surface of the jacket facing away from the heart. In this embodiment, the non-adherent material prevents unwanted fibrosis of or

adhesions to surrounding tissues. Alternatively, the non-adherent material can be configured to be a hydrogel material that fills interstitial spaces of the jacket. It will be apparent to one of skill in the art that the non-adherent material can be configured to prevent undesirable fibrosis or other damage to any target tissue.

5           The non-adherent material can be adapted to cover any desired surface of the heart, such as the entire surface of the heart, or selected areas of the heart only. In one embodiment, the material can be fabricated to line the entire jacket, thus covering the entire epicardial surface of the heart that would otherwise be in contact with the jacket.

10           Removal of the jacket at selected sites may be required to access the coronary arteries in order to form an anastomotic site for coronary artery bypass in patients who received the device of the invention but subsequently develop coronary artery disease requiring bypass. Placement of non-adherent material at these  
selected sites facilitates removal of the jacket and access to these arteries. In one  
15           embodiment shown in Figure 8, the non-adherent material 30 is placed at strategic sites between the jacket 10 and the epicardial surface of the heart, to allow access to the coronary vessels. For example, the non-adherent material is placed to cover only the epicardial course of the major coronary arteries. This will allow a surgeon to remove part of the jacket if coronary artery bypass surgery is deemed necessary in a  
20           patient who received the device of the invention in the past.

          Alternatively, the non-adherent material is placed at strategic base-to-apex locations to allow relief of constriction. In one embodiment shown in Figure 9, the non-adherent material 32 preferably forms ribs 34 that course from base to apex of the heart. Preferably, the ribs are provided a finite distance apart along the device.  
25           This embodiment is desirable should the jacket cause constriction of the heart. The ribs allow the surgeon to score the jacket at the rib sites in the event a patient develops a constrictive or restrictive pattern as a result of the jacket. Relief of constriction is desirable in certain patients. For example, constrictive physiology may occur in some patients as a result of the presence of the jacket and pressure of  
30           the heart during diastole. This may in turn require removal of the jacket.

          The non-adherent material is fabricated from any suitable material that provides the desired properties. In one embodiment, the non-adherent material is

fabricated from the same material used to fabricate the jacket 10, for example, polyesters, PTFE, polypropylene, polyurethane, silicone, and the like. In yet another embodiment, the non-adherent material is fabricated from a different material than the jacket 10. Another example of suitable non-adherent material is available  
5 commercially under the brand name GORE-TEX™. In yet another embodiment, the non-adherent material is fabricated from a hydrogel, as described herein. The non-adherent material can be flexible or rigid, depending upon the desired application. Given the present teaching, one of skill in the art can select a suitable non-adherent material.

10 The non-adherent material is provided, in one embodiment, as a separate element of the device. For example, the non-adherent material can be provided as a separate lining that is placed between the jacket and the surface of the heart, or on the outside surface of the jacket, facing away from the heart. In yet another embodiment, the non-adherent material of the invention is provided as a coating on  
15 the jacket of the device.

The device of the invention can include non-adherent material and can optionally further include antifibrotic agents, if desired. Placement of the non-adherent material, when provided as a separate element of the device, is accomplished at any suitable time during application of the jacket, for example, prior  
20 to, during, or after placement of the jacket on the heart. When provided as a separate element of the device, the non-adherent material is held in place on the heart surface by the jacket 10. In this embodiment, the snug fit of the jacket 10 is sufficient to maintain the desired location of the non-adherent material on the heart.

Alternatively, the non-adherent material is attached to the jacket 10. In this  
25 alternative embodiment, attachment of the non-adherent material to the jacket, and the attachment of the jacket 10 to the heart (as discussed *supra*) maintains placement of the non-adherent material. Securement of the non-adherent material to the jacket can be accomplished using any suitable means, such as, for example, sutures, staples, bioadhesives, or the like. Given the description herein, one of skill in the art  
30 can readily choose suitable methods for securing the non-adherent material to the jacket.

The non-adherent material can be fabricated to be permeable to therapeutic

agents, so that the material does not interfere with delivery of the agent(s) to the heart. Alternatively, the non-adherent material is impermeable to therapeutic agent(s), for example, when there is no concern with interference of delivery of the therapeutic agent(s), such as when the location of the non-adherent material is  
5 separate from the location of any therapeutic agents included in the device.

The jacket 10 is low-cost, easy to place and secure, and is amendable to use in minimally invasive procedures. The thin, flexible fabric 18 permits the jacket 10 to be collapsed and passed through a small diameter tube in a minimally invasive procedure.

10 The jacket 10 can be used in early stages of congestive heart failure, such as myocardial infarction or congestive heart failure, or late stages, such as chronic dilated cardiomyopathy. For patients facing cardiac enlargement due to viral infection, the jacket 10 permits constraint of the heart H for a sufficient time to permit the viral infection to pass. In addition to preventing further heart  
15 enlargement, the jacket 10 treats valvular disorders by constraining circumferential enlargement of the valvular annulus and deformation of the ventricular walls.

The jacket 10, including the knit construction, freely permits longitudinal and circumferential contraction of the heart H (necessary for heart function). Unlike a solid wrap (such as a muscle wrap in a cardiomyoplasty procedure), the fabric 18  
20 does not impede cardiac contraction. After fitting, the jacket 10 is inelastic to prevent further heart enlargement while permitting unrestricted inward movement of the ventricular walls. Further, the jacket permits unrestricted diastolic filling of the heart. The jacket prevents overstressing or stretching of the ventricle at the end of diastole. The open cell structure permits access to coronary vessels for bypass  
25 procedures subsequent to placement of the jacket 10. Also, in cardiomyoplasty, the latissimus dorsi muscle has a variable and large thickness (ranging from about 1 mm to 1 cm). In contrast, the material of the jacket 10 is uniformly thin (less than 1 mm thick). The thin wall construction thus reduces the risk of fibrosis and minimizes interference with cardiac contractile function.

30 Animal test studies on the jacket of the invention show the efficacy of the jacket of the present invention. Test animals were provided with the device 10 of Fig. 3. The animals' hearts were rapidly paced to induce heart failure. After six

weeks, animals without the device experienced significant heart enlargement while those with the device experienced no significant enlargement. Further, animals with the device had significantly reduced mitral valve regurgitation and had improved contractability as measured by ejection fraction.

5           The jacket described above is used in connection with a delivery source for the delivery of a therapeutic agent to the surface of the heart. As used herein, a “therapeutic agent” is an agent that assists in the treatment, cure, relief or prevention of disease or disorders of the heart or surrounding tissue. Therapeutic agents function by affecting the structure or function of the tissue treated, to have the  
10   desired effect.

          The present invention provides a device and method for localized, targeted delivery of a therapeutic agent to a target area of the heart and/or of surrounding tissues. As used herein, “target,” “target area” and “target tissue” refer to a selected site of the heart, or of tissues surrounding the heart, intended to be treated using the  
15   present invention. As contemplated in the present invention, the target tissue can comprise any desired area to be treated with a method or device of the invention, including, for example, a specific area of the heart (such as an area of ischemia or necrosis, or one or more diseased or damaged arteries), the entire surface of the heart, or selected tissues surrounding the heart (such as the lung or pericardium).  
20   Further, after delivery to the surface of the target tissue, such as the heart, the therapeutic agent can penetrate the tissue surface and thereby act below the surface of the tissue.

          As contemplated in the present invention, therapeutic agents include one or more pharmacological agents, cellular material, and/or combinations thereof. While  
25   the present application provides examples of suitable therapeutic agents, the disclosure hereof should not be interpreted to be so limited. The discussion of particular exemplary therapeutic agents herein is not meant to be limiting; rather, the disclosure should be interpreted to encompass suitable therapeutic agents within the scope of the invention.

30           Suitable pharmacological agents include chemicals or pharmacological compounds that affect the target tissue, such as the heart and/or surrounding tissues, and its processes. Examples of suitable pharmacological agents include anti-

arrhythmic drugs, thrombolytic agents, anti-restenotic agents, anti-inflammatory or anti-fibrotic agents, anti-apoptotic agents, antibiotics, neurohormone inhibitors, antineurohormone agonists, leukocyte inhibitory factor antagonists, glycoprotein 130 antagonists, anti-immune rejection agents, inhibitors of matrix

- 5 metalloproteinases, agents that prevent calcification, agents that increase intracellular calcium without activating  $\beta$ -adrenergic receptors, metabolic factors, nucleic acid molecules, and other comparable agents capable of treating, curing, relieving or preventing disease or disorders in target tissues.

As contemplated by the present invention, anti-arrhythmic drugs are  
10 compounds that act to inhibit arrhythmia (that is, abnormal cardiac rhythm) and stabilize normal sinus rhythm to the heart. Examples of anti-arrhythmic drugs include those classified as type I (such as lidocaine, procainamide, encainide, flecainide), type II (for example,  $\beta$ -adrenergic blocking agents such as norepinephrine, epinephrine, isoproterenol, propranolol, dobutamine), and type III  
15 (such as ibutilide and sotalol), as well as quinidine, phenytoin, angiotensin converting enzyme (ACE) inhibitors, nitroglycerin, hydralazine, captopril, and calcium channel blockers such as verapamil, nifedipine, and diltiazem.

Thrombolytic agents are compounds that act to dissolve or split up clots in the body. Examples of suitable thrombolytic agents include streptokinase,  
20 urokinase, tissue plasminogen activator (TPA), and the like.

In another embodiment, the therapeutic agent of the present invention comprises one or more anti-restenotic agents. As used herein, anti-restenotic agents are agents that inhibit restenosis (i.e., cell proliferation) and/or extracellular matrix synthesis at the level of atherosclerotic plaque, of coronary arteries following  
25 percutaneous transluminal coronary angioplasty, or vascular grafts following coronary artery bypass grafting procedures. Examples of suitable anti-restenotic agents include anti-thrombotic agents (such as heparin and ReoPro), and radionuclide emitters, and the like.

Alternatively, the therapeutic agent of the present invention comprises one or  
30 more anti-inflammatory or anti-fibrotic agents. Such anti-inflammatory or anti-fibrotic agents are agents that inhibit scar formation associated with aberrant fibrosis and prevent formation of epicardial fibrosis, which could interfere with diffusion of

other agents from the device of the present invention to the target tissue and could increase resistance to electric current flow, thus requiring a pacemaker to deliver more voltage. Examples of suitable anti-inflammatory or anti-fibrotic agents include steroids, such as dexamethasone and the like, and lathrogenic agents such as

5 penicillamine, n-acetyl-cysteine,  $\beta$ -aminopropionitrile, and the like.

In another embodiment, the therapeutic agent is provided in the form of a metabolic effector. As used herein, a metabolic effector represents a biologically active molecule that is capable of altering activity in a metabolic pathway. Thus, a metabolic effector is able to alter biological response elicited by intermediates, or

10 final products of a metabolic pathway. Such effectors may be enzymes, enzyme inhibitors or stimulators, neurohormones, hormones, and the like. Examples include natural and pharmaceutical agents intended to serve as antagonists or agonists, with specific binding activity to enzymes involved in neurohormone metabolism, or cell membrane-bound receptors of such neurohormones. Among these metabolic ..

15 effectors are ACE inhibitors, which inhibit angiotensin converting enzyme and metabolic conversion of angiotensin I to angiotensin II, thiorphan, which inhibits neutral endoprotease and prevents metabolic breakdown of atrial natriuretic peptide, spironolactone,  $\beta$ -blockers, and losartan. These latter three effectors are antagonists of aldosterone, catecholamines (such as norepinephrine), and angiotensin II,

20 respectively, and thus inhibit receptor binding, and biological response normally elicited by these natural metabolites.

Alternatively, the therapeutic agent can be provided in the form of a therapeutic gene that functions to assist in the treatment, cure, relief or prevention of disease or disorders of the heart or surrounding tissue. As used herein, a

25 "therapeutic gene" is a segment of nucleic acid that specifies a particular protein or polypeptide chain that, when expressed, provides a therapeutic effect. Many such therapeutic genes are known in the art to provide beneficial effects in the treatment of cardiac disease or disorders. For example, suitable therapeutic genes function to prevent restenosis, promote angiogenesis, modulate pathways of electrical

30 conductance to control cardiac arrhythmias, enhance the wound healing process (for example, using such growth factors as TGF- $\beta$ ), or express thrombolytic agents such as tissue plasminogen activator (TPA) or urokinase.



In this embodiment, the therapeutic agent comprises one or more gene agents, such as naked gene plasmids, oligonucleotides, ribozymes, and viral vectors containing genes encoding specific transgene products. Such gene agents provide mechanisms for introducing genes into the target area, to promote expression of a transgene product.

When provided in the form of nucleic acid, the therapeutic agent can be provided through a delivery system, such as liposomes, microspheres, nanospheres, and polymer matrices, or may be provided as naked nucleic acid. When provided with a polymer matrix, the nucleic acid can be either entrapped or dispersed into the polymer matrix or adsorbed onto the surface. Polymers can be provided as biodegradable materials such as polyesters or polyanhydrides or blends thereof; nonbiodegradable materials such as ethylene vinyl acetate copolymers; or natural materials such as collagen or gelatin.

Suitable pharmacological agents can be surface-acting or can penetrate the myocardium. For example, small molecule compounds are capable of penetrating the myocardium to act beneath the surface of the heart. Examples of small molecule compounds that are capable of penetrating the MYO include anti-arrhythmic agents, lathrogenic agents, such as penicillamine, N-acetyl-L-cysteine, and 3-aminopropionitrile fumarate, and the like.

When the therapeutic agent comprises a pharmacological agent, the agent can be provided with any suitable carrier diluent, filler, binder or other excipient, depending upon the composition of the delivery source and the dosage desired, for delivery of the agent to the target tissue. By "carrier" is meant a pharmaceutically acceptable carrier that is conventionally used in the art to facilitate the storage, administration, and/or healing effect of the agent. A carrier may also reduce any undesirable side effects of the agent. A suitable carrier should be stable, i.e., incapable of reacting with other ingredients of the formulation. It should not produce local adverse effects in recipients at the dosages and concentrations employed for treatment. Such carriers are generally known in the art. See Remington's Pharmaceutical Sciences, 16<sup>th</sup> edition, Olso, A. ed. (1980).

In another embodiment, the therapeutic agent of the present invention is provided in the form of cellular material. As contemplated in the present invention,

cellular material means material that is obtained from differentiated cells with a different phenotype (such as smooth muscle cells, endothelial cells, and fibroblasts) or with the same phenotype (such as myocardial cells). Alternatively, the cellular material is obtained from non-differentiated cells, such as mesenchymal cells.

5 Cellular material is introduced to the heart to repair, replace or enhance the biological function of damaged cells in order to strengthen a weakened heart. Suspensions of cellular material can be injected into diseased cardiac tissue, and the implanted cells become important contributors towards normalization of structure and function of diseased tissue. In one preferred embodiment, cellular material is  
10 injected into the myocardium, which leads to incorporation of the cells into the tissue, cell contraction synchronous with adjacent cells, and an improvement in cardiac hemodynamics. Cellular material includes myogenic cells, endocrine cells, islet cells, and any other suitable cell type desired for application using the invention described herein.

15 The cells may be of a single tissue type or may contain a mixed population of cells. The cell culture may include cells that are xenogenic, allogenic and/or isogenic to the host in which they are implanted. Propagation of vertebrate cells in culture is well known in the art (See, e.g., Tissue Culture, Academic Press, Kruse and Patterson, editors (1973)).

20 The implanted cellular material may include culture media. Those of skill in the art are familiar with cell culture media. Examples of commercial available media include Ham's F10 (Sigma), Minimal Essential Medium ("MEM", sigma), RPMI-1640 (Sigma), and Dulbecco's Modified Eagle's Medium ("DMEM", Sigma). The media may be supplemented as necessary with hormone and/or other  
25 growth factors, salts, buffers, nucleosides, antibiotics and trace elements (inorganic compounds usually present at final concentrations in the micromolar range). Alternately, the delivery source may allow nutrients to diffuse into the cavity to support the live cell culture.

In one embodiment, the implanted cells produce a therapeutic agent that has  
30 a beneficial effect on the host. In this embodiment, the therapeutic agent can comprise one or more of the therapeutic agents discussed *supra*.

In one embodiment of the invention, the implanted cells can be genetically

engineered transformed cells. As used herein, the term "transformed cells" refers to cells in which an extrinsic DNA or gene construct has been introduced such that the DNA is replicable, either as an extrachromosomal element or by chromosomal integration. Transformation of the cells is accomplished using standard techniques  
5 known to those of skill in the art and is described, for example, by Sambrook et al., Molecular Cloning: A Laboratory Manual, New York, Cold Spring Harbor Laboratory Press (1989).

Extrinsic DNA or gene construct refers to a nucleic acid sequence originating outside a recipient cell and introduced into a recipient cell by a DNA delivery  
10 technique. A DNA or gene construct may be manufactured using recombinant DNA technology known in the art, or may be a nucleic acid fragment purified from a source material. The extrinsic gene may be entirely composed of homologous sequence, i.e., sequences cloned, isolated, or derived from the same species from which the recipient cells derive. Alternatively, all or a portion of the extrinsic gene  
15 may be composed of sequences from species other than the species from which the recipient cells derive, hereinafter termed heterologous sequences. The extrinsic gene construct may be natural in that none of the regulatory sequences and coding sequences that may be a part of the gene are substantially or intentionally altered, or the extrinsic gene construct may be chimeric in that sequence fragments from  
20 various sources are present in the final gene construct.

In one embodiment, cellular material is selected from smooth muscle cells, endothelial cells, mesenchymal stem cells, and fibroblasts and is introduced into the cardiac environment using transdifferentiation. Transdifferentiation is a procedure such as that described by Kessler et al., that involves the conversion of a committed,  
25 differentiated, or specialized cell to another differentiated cell type with a distinctly different phenotype (See Myoblast Cell Grafting Into Heart Muscle: Cellular Biology and Potential Applications, P.D. Kessler et al., *Annu. Rev. Physiol.* 1999, 61:219-42). In the present invention, smooth muscle cells, endothelial cells, mesenchymal stem cells, and/or fibroblasts from a donor can be provided in  
30 connection with the delivery source (e.g., the cells can be seeded onto the surface of the delivery source, as discussed in more detail below), to provide a source of cellular material for transdifferentiation.

In another embodiment, the cellular material comprises myogenic cells that are grafted onto the surface of the heart. In this aspect, new myogenic cells, such as cardiomyocytes, are introduced into the myocardium for repair of the heart. As used herein, grafting includes coating or impregnating cardiomyocytes onto or within the delivery source for application to the surface of the heart, or injecting  
5 cardiomyocytes into the heart muscle through direct epicardial injection. Preferably, myogenic cells are harvested from the patient receiving treatment, to minimize rejection of the cells.

In one embodiment, the jacket material serves as a scaffold onto which the matrix material containing the therapeutic agent is attached. For example,  
10 contractile cells can be seeded or sodded into/onto the jacket in such a way that the jacket material serves as a scaffold for support of the cells. As described herein, the cells can be harvested from a patient culture and applied to the jacket material. Alternatively, mesenchymal cells can be harvested from another patient and applied  
15 to the jacket material. In either event, these cells can then be adapted to perform contractile work, much in the way that skeletal muscle is adapted to the requirements for contraction in association with cardiomyoplasty. Cells implanted on/in the jacket can be exposed to an oriented electric field in such a way that the cells orient into a contractile element. Optimally, the biocompatible material comprising the material of the jacket is itself designed and oriented in the proper direction(s) of  
20 muscle contraction (i.e., in line with muscle fibers of the heart). The cells contained on the device are then capable of being stimulated using an electronic pacemaker, synchronous with the heart. Approaches to replacing myocardial scar tissue with cardiac cells are discussed, for example, by Li et al., in Cell Therapy to Repair Broken Hearts, Can. J. Cardiol. 14, 5: 735-744 (1998).  
25

Myocardial cells, or other viable cell population can be attached to the jacket by various specific and non-specific means. Cells can be cultured directly onto the fabric of the jacket. Under suitable circumstances, cells can be promoted to completely cover the jacket surface. In the case of myocytes, the cells can be made  
30 to contract synchronously, perhaps providing a synthetic active contractile element to support the heart. Attachment of cells to the jacket can be via a spacer arm covalently attached to the jacket backbone polymer. This spacer arm, typically

consisting of a string of methylene groups, or natural or synthetic peptides, is structured to have a biologically active attachment group at its terminus, which would interact with a receptor on the cell surface. One example would be use of a poly-lysine peptide (or other such backbone) which terminates with an rgd (arginine-  
5 glycine-aspartic acid) sequence. The rgd sequence is known to bind with specific cell surface receptors, stabilizing attachment of cells. Similar examples have been used in construction of prosthetic vascular grafts, in which rgd peptides are incorporated into the graft to facilitate binding and stabilization of endothelial cells.

Cellular material introduced to the surface of the heart has a variety of  
10 clinical applications. For example, implanted cells can provide a platform for protein delivery at the surface of the heart. In this embodiment, cells provide a continual source of protein delivery at the surface of the heart to promote myocardial repair and to enhance growth of the transplanted cells. For example, myocytes can be altered genetically to deliver recombinant TGF- $\beta$ 1 or other effector to the heart.  
15 Additionally, neurotrophic factors and/or angiogenic factors, such as vascular endothelial growth factor or fibroblast growth factor, can be locally expressed to avoid the potentially harmful effects of systemic delivery of these proteins.

The delivery source of the invention can be provided in a variety of suitable forms. In one embodiment, the delivery source comprises a coating that is provided  
20 on, and/or impregnated into, the material of the jacket. Alternatively, the delivery source comprises a separable delivery source that is provided in association with the jacket.

In one embodiment, the delivery source is provided as a coating on, and/or impregnated into the material of, the jacket of the device. In this embodiment, the  
25 coating comprises a matrix material and one or more therapeutic agents. As used herein, the matrix material is a biologically and pharmacologically compatible and/or biodegradable material that can be adapted to include one or more therapeutic agents. Preferably, the matrix material is flexible and permeable to the therapeutic agent, to provide a suitable source for controlled release of the agent. Examples of  
30 suitable matrix materials include and polymeric matrix materials and hydrogels.

The coating can be applied to the jacket in any suitable fashion, using methods known in the art, e.g., by dipping, coating, spraying, or impregnating the

coating onto the jacket. The porous, knit biocompatible jacket material, as described herein, is particularly well suited for application of the therapeutic agent by coating or impregnation. The coating can be provided on the fibers 20 that form fiber strands 21a and 21b of the knit jacket material only, or the coating can be provided as a uniform coating of both the fibers 20 and the open cells 23 of the jacket. The viscosity of the coating will determine whether the coating is provided as a coating of the fibers only or as a uniform coating of the fibers and open cells. Viscosity of the coating is determined by such factors as the percent solids of the coating, and the molecular weight of the polymer.

10           The knit material of the jacket provides numerous advantages in connection with the delivery source. In one embodiment, the coating is provided on the individual fibers that form fiber strands 21a and 21b of the knit jacket. As described above, the individual fibers are interwoven along axes  $X_a$  and  $X_b$ . The interwoven fiber strands provide an increased surface area for coating, as compared to single  
15 fiber strands or strands that are provided in side-by-side arrangement. Also, coating along the fibers only maintains the open, interstitial spaces of the knit, which in turn provides advantages of the material mentioned above.

          Alternatively, the coating is provided as a uniform coating that not only coats the fibers, but also fills the interstitial spaces of the jacket. In this embodiment, the  
20 overall surface area of the delivery source is further increased, as the coating is provided not only on the surfaces of the fibers of the jacket, but also fills the interstitial spaces defined by the fibers. The interstitial spaces serve as reservoirs for the coating, providing spaced-apart areas of concentrated coating containing the therapeutic agent. At the same time, the advantages of the jacket are maintained,  
25 such as the flexibility of the jacket and contact with the heart that is intimate and non-shifting.

          Whether the coating is provided along the fiber strands only, or over both the fiber strands and open cells, the flexibility of the jacket is maintained. The directional expansion properties of the knit material allows the delivery source of the  
30 device to maintain intimate contact with the surface of the heart so that one or more therapeutic agents can be released directly to the surface of the heart and/or target tissue surrounding the heart. The coating itself is sufficiently flexible so that it does

not fracture and fall or peel off the material, but rather expands along with the jacket material. Further, because the jacket surrounds the heart and expands along with the heart during its natural movement, the delivery source is maintained in intimate contact with the surface of the heart for prolonged periods of time. The device is not  
5 loosened by natural movement of the heart, and therefore delivery of one or more therapeutic agents that is intimate and non-shifting can be provided for prolonged periods of time.

The coating can be provided at any suitable location on the jacket, including a selected portion, or the entire surface area, of the jacket. For example, a portion of  
10 the jacket overlying an area of ischemia can be provided with suitable therapeutic agents in that selected area only, while anti-fibrotic agents can be provided on another selected area, or the entire area, of the jacket at the same time. The method of coating the jacket can be modified to achieve the desired coating area.

The coating on the jacket is provided in suitable thickness to provide an  
15 adequate dosage of the agent to achieve the desired effect, while controlling the release of the agent to the target tissue. Other factors influencing the thickness of the coating include the size of the therapeutic agent, release kinetics of the agent, and hydrophobicity or hydrophilicity of the agent versus the coating. At the same time, the coating is not provided in a thickness that would adversely affect the  
20 flexibility of the jacket material. For example, as the thickness of the coating increases, the mass that the heart is required to move during diastole increases. As a result, the thicker the coating, the less flexible the jacket becomes, and the greater the risk of fibrosis from the jacket. As presently contemplated, the final (total) thickness of the coating is generally in the range of approximately 0.5 mm to  
25 approximately 4 mm, preferably in the range of approximately 0.5 mm to approximately 2 mm, and optimally in the range of approximately 0.5 mm to approximately 1 mm. However, it is to be understood that the final thickness of the coating can be adjusted to any suitable thickness that provides the advantages and characteristics herein described. The coating can be formed by applying a single  
30 coating, or by applying multiple coatings to achieve a final desired thickness.

The matrix material of the coating is preferably a polymeric material or a hydrogel. Preferred polymeric materials are those that have a low degree of

- crystallization, and are biocompatible. In one embodiment, the polymeric matrix material is biodegradable. Examples of biodegradable polymers that can be used in this embodiment include polylactides, polyglycolides, polycaprolactones, polyanhydrides, polyamides, polyurethanes, polyesteramides, polyorthoesters,
- 5 polydioxanones, polyacetals, polyketals, polycarbonates, polyorthocarbonates, polyphosphazens, polyhydroxybutyrates, polyhydroxyvalerates, polyalkylene oxalates, polyalkylene succinates, poly(malic acid), poly(amino acids), polyvinylpyrrolidone, polyethylene glycol, polyhydroxycellulose, chitin, chitosan, and copolymers, terpolymers, or combinations or mixtures of the above materials.
- 10 The matrix material can also be provided in the form of a hydrogel. In this embodiment, the therapeutic agent(s) are released from the matrix by diffusion and/or degradation of the matrix material.

In an alternative embodiment, the polymeric matrix material is non-degradable, so that the matrix material remains part of the implanted device and is

15 not broken down over time. Examples of suitable non-degradable materials include, for example, polyurethanes (such as polyether polyurethane), or silicone rubber materials (such as polydimethylsiloxane derivatives). In this embodiment, the therapeutic agent is released by diffusion of the agent through the matrix material.

Preferably, because both the degradable and non-degradable materials are

20 intended to remain in the body for extended periods of time, these materials do not contain any leachable components that may be toxic to tissues.

Depending upon the desired softness and flexibility of the coating, and rate of release of the therapeutic agent, the amount and type of polymer can be varied to produce the desired result. For example, for a relatively soft and flexible polymer

25 matrix, copolymers with a low Tg can be used, primarily the lactide/caprolactone copolymers.

Preferably, the polymeric material is provided with a solvent that is non-toxic and biocompatible. Examples of suitable solvents include N-methyl-2-pyrrolidone, 2-pyrrolidone, ethanol, propylene glycol, acetone, methyl acetate, ethyl acetate,

30 methyl ethyl ketone, dimethylformamide, dimethyl sulfoxide, dimethyl acetamide, tetrahydrofuran, caprolactam, decylmethylsulfoxide, oleic acid, and 1-dodecylazacycloheptan-2-one. One of skill in the art could readily determine the



appropriate solvent for the polymeric matrix material, using such factors as crystallinity, hydrophilicity, hydrogen-bonding and molecular weight of the polymeric material.

Typical application of a coating of the invention is as follows. The  
5 therapeutic agent(s) to be applied to the jacket are dissolved in a suitable solvent, such as dimethyl acetamide. In one embodiment, the therapeutic agent is soluble in the solvent, and a homogenous solution of the polymer and drug are applied to the jacket. Alternatively, the drug is not soluble in the solvent, and a suspension or dispersion of the drug in the solvent will result. The matrix material is also  
10 dissolved in the solvent. The therapeutic agent solution and matrix material solution are mixed, preferably forming a homogenous solution, although the solution may form a non-homogenous suspension. In either embodiment, the solvent will dissipate and the polymer solidifies and entraps or encases the therapeutic agent within the solid matrix.

15 The matrix material/therapeutic agent solution is then applied to the jacket, for example, by dip coating or other suitable method. The coated jacket is removed from the solution and optionally dried. The jacket is dried, for example, in a vacuum oven, or may be air dried, to evaporate the solvent from the jacket. The result is a thin film of the matrix material/therapeutic agent.

20 After placement of the device on the surface of the heart, the therapeutic agent is released from the coating into adjacent tissues by diffusion through the pores of the matrix material, and/or polymeric matrix degradation mechanisms. The rate and extent of release of the therapeutic agent from the delivery source are controlled over a range of speeds and amounts. Release of the therapeutic agent  
25 from the solid matrix will follow the same general rules for release of a therapeutic agent, such as a drug, from a monolithic polymeric device. Additionally, when the matrix material comprises a hydrogel polymer, the matrix material can be fabricated so that it swells in an aqueous environment, such as the body. In this embodiment, the hydrophilicity of the hydrogel can be altered (for example, by altering the  
30 polarity of the matrix material) to permit the desired water uptake. Such swelling of the matrix provides communication between the matrix and the adjacent tissues for delivery of a therapeutic agent.

Factors influencing the release rate include characteristics of the therapeutic agent, and characteristics of the overall coating. Characteristics of the therapeutic agent that influence release rate include water solubility, distribution within the matrix, concentration within the coating, chemical nature of attachment to the matrix material (i.e., chemical bond, if any), molecular weight, hydrophilicity or hydrophobicity, physical form, and the like. For example, release of a therapeutic agent having a low solubility in water, such as a lipid or other hydrophobic molecule, typically requires the degradation of a substantial part of the polymeric matrix to expose the material directly to the surrounding target tissue fluids.

10 The release rate is also influenced by characteristics of the overall coating that comprises a matrix material and therapeutic agent. For example, the polymeric matrix can be formulated to degrade after an effective and/or substantial amount of the therapeutic agent is released from the matrix. The release rate can be affected by the size and shape of the coating; material type and molecular weight of the matrix material; solubility, biodegradability, and/or hydrophilicity of the coating; permeability factors involving the therapeutic agent and the particular matrix material; degradation of the matrix; and the concentration and kinds of other additives present, if any, within the coating. Depending upon the therapeutic agent selected for use in the invention, the above parameters can be adjusted to give the desired rate and duration of release.

Generally, the thicker the coating, the greater the coating volume, and thus the amount of agent that can be incorporated into the coating. Consequently, a greater amount of a therapeutic agent can ostensibly be delivered from a thicker coating, and delivery can be tailored to occur over a greater time course. Other factors can influence delivery rate. Porosity in the coating, reflecting coating composition and density, can impact the ease of movement of therapeutic agents from the coating into adjacent cardiac tissue. Coating composition and chemical structure of the therapeutic agent or agents can influence the nature of interaction between these materials. If the therapeutic agent exhibits strong interaction with the coating, then the rate of release will be slow. For example, a polyurethane matrix coating containing hydrophilic moieties can be fashioned to provide a rapid release

vehicle for hydrophilic therapeutic agents. Likewise, a hydrophobic therapeutic agent will have slow release kinetics from a hydrophobic polymer coating.

Optionally, the matrix material is formulated to provide an initial burst effect. This results in a bolus dose of the therapeutic agent, followed by a relatively  
5 constant release of the agent over time. Factors contributing to a greater initial burst include the thickness of the coating, the particle size of the therapeutic agent, and amount of therapeutic agent included in the coating. For example, factors contributing to a greater initial burst include greater thickness of the coating, larger particle size of the therapeutic agent, and higher amount or concentration of the  
10 therapeutic agent.

The present invention provides a device that is capable of delivering a range of doses of therapeutic agent over prolonged periods of time. The amount of therapeutic agent incorporated into the coating is determined by the patient's physician. This amount depends upon such factors as the desired release profile,  
15 concentration of the drug required for a therapeutic effect, and length of time that the therapeutic agent has to be released for effective treatment. For example, a coating containing a higher weight percent of therapeutic agent will generally release a higher total amount of therapeutic agent to the target tissue. According to the invention, the coating contains approximately 1% (by weight) to approximately 40%  
20 (by weight) of the therapeutic agent. Preferably, the coating contains approximately 5% (by weight) to approximately 30% (by weight) of the of the therapeutic agent, more preferably, approximately 10% (by weight) to approximately 15% (by weight).

In one embodiment, as the polymeric matrix degrades, the therapeutic agent is released from the delivery source. The delivery source will release the therapeutic  
25 agent within the matrix at a controlled rate until the therapeutic agent is depleted. With certain therapeutic agents, the polymer will degrade after the agent has been completely released. With other therapeutic agents such as peptides or proteins, the agent will be completely released only after the polymer has degraded to a point where the non-diffusing drug has been exposed to the body fluids.

30 In one embodiment, the matrix material of the coating is provided in the form of a hydrogel polymer. In this embodiment, the hydrated polymer matrix allows controlled release of the therapeutic agent to the target tissue. As discussed *supra*,

the thickness of the hydrogel is controlled to vary the rate of release of the therapeutic agent. In contrast, when rapid release of the agent is desired, the thickness of the hydrogel is decreased. The ratio of therapeutic agent to hydrogel polymer in the matrix is adjusted to provide the desired release rate and dosage over  
5 time. Preferably, the hydrogel comprises at least 80% (v/v) water.

The hydrogel polymer is selected from polycarboxylic acids, water-swollen cellulose derivatives, gelatin, polyvinylpyrrolidone, maleic anhydride polymers, polyamides, poly(vinyl alcohol), polyethylene oxides, poly(2-hydroxyethyl methacrylate), poly(ethylene oxide), and copolymers thereof.

10 In one embodiment, the hydrogel polymer is characterized by the ability to incorporate a substantial amount of the therapeutic agent, typically in aqueous form, and is swellable such that the aqueous therapeutic agent solution can be effectively squeezed out of the coating when pressure is applied by natural expansion of the heart during diastole. The therapeutic agent is thus applied to the tissue in a gentle  
15 manner that avoids disrupting or injuring healthy cardiac or other tissue, while diffusion of the therapeutic agent into the tissue is facilitated by the application of the pressure exerted during diastole. At the same time, pressure between the heart and the jacket effectively forms a seal that prevents the therapeutic agent from diffusing to areas in the body other than the treatment area. The hydrogel polymer  
20 can be biodegradable or non-degradable, as described above for the polymeric matrix material.

Alternatively, the delivery source comprises a chemical/polymer bioadhesive system used to adhere the device of the invention to the heart. The polymer system used for adhesion of the jacket to the heart is modified to include one or more  
25 therapeutic agent(s). The amount of therapeutic agent included in the bioadhesive system is influenced by such factors as listed above, including desired dosage of the agent, solubility of the agent, and the molecular weight of the agent versus the molecular weight of the polymer. Moreover, how the agent loading affects the physical and/or chemical characteristics of the polymer bioadhesive will be  
30 considered.

In another embodiment of the present invention, the delivery source is provided as an element that is separate from the jacket of the device. The delivery

source can be provided in the form of a patch containing the therapeutic agent of interest, or a bladder containing the therapeutic agent. Suitable patches and bladders are known in the art. For example, see Epicardial Administration of Ibutilide from Polyurethane matrixes: Effects on Defibrillation Threshold and Electrophysiologic Parameters, Labhasetwar et al., J. Of Cardiovascular Pharm., 24:826-840 (1994),  
5 Sotalol Controlled-Release Systems for Arrhythmias: In Vitro Characterization, In Vivo Drug Disposition, and Electrophysiologic Effects, Labhasetwar et al., J. of Pharm. Sciences, 83: 156-164 (1994).

When the delivery source comprises a bladder, the bladder is preferably  
10 refillable. Refilling the bladder can be achieved in any suitable manner, e.g., using a catheter connected to the bladder containing a proximal terminal connection just under the surface of the skin, or through a one-use direct injection of therapeutic agent from a disposable hypodermic needle.

In this embodiment, the jacket provides an anchoring surface for the delivery  
15 source that presses the delivery source against the surface of the heart and maintains the delivery source in position on the heart. According to the invention, the patch or bladder can be provided underneath the jacket 10, such that the delivery source is positioned between the jacket and the heart. The jacket presses the delivery source against the heart, without causing damage to the heart that would result from directly  
20 attaching the source at the treatment site, by sutures, adhesives or the like. The delivery source can be attached to the jacket, for example, using sutures or bioadhesives, to maintain the position of the delivery source in relation to the jacket. Alternatively, the patch or bladder can be held in place simply by the pressure of the jacket against the heart. Because the jacket itself is maintained in non-shifting  
25 contact with the heart, the delivery source is also provided with a non-shifting position on the surface of the heart. For example, the use of the jacket to maintain the positioning of the delivery source avoids such undesirable effects as fibrosis, necrosis, and the like.

The patch or bladder is fabricated from a biocompatible material, to avoid  
30 adverse effects associated with rejection, infection, and the like. The amount of therapeutic agent provided in such patches or bladders depends upon such factors as those listed above for the delivery source as a coating.

Delivery of the therapeutic agent to target tissues can be achieved through passive as well as active delivery methods. Passive methods include diffusion of the agent from the delivery source, as discussed above. Active delivery mechanisms use an energy source to deliver the therapeutic agent to the target tissue.

5 Active delivery systems include systems that use an energy source to deliver one or more therapeutic agents to the target tissue. Suitable energy sources include external sources such pumps or sources of electrical current. For example, an osmotic pump can be used in connection with a bladder delivery source, to provide active delivery of agents from the bladder to target tissues. Examples of sources of  
10 electrical current include batteries and electrodes. For example, the device of the invention can utilize iontophoresis to deliver one or more therapeutic agents to the heart. Iontophoresis uses electrical current, through a direct myocardial electrode patch, to transport charged molecules into tissue. Iontophoretic methods are known in the art, as are methods using phonophoresis and battery-driven devices. Other  
15 suitable external energy sources include ultrasound, thermal energy, radiofrequency, or microwave energy.

In yet another embodiment, the natural movement of the heart is used as an energy source for therapeutic agent delivery. As described above, when the delivery source of the invention comprises a hydrogel, diastolic filling of the heart can drive  
20 release of the therapeutic agent from the hydrogel coating. In this embodiment, the hydrogel can be selected to allow release of a desired dosage of the therapeutic agent from the hydrogel polymer coating during compression of the hydrogel polymer coating against the heart or other tissue. The pumping action of the heart induces the device to release the agent, and the therapeutic agent is effectively released upon  
25 compression of the polymer coating on the device. When the heart expands during diastole, it exerts pressure against the jacket of the device, which in turn compresses the coating against the heart. Compression of the coating triggers release of the agent for transfer into or onto the target tissue. The pressure applied to the fluid therapeutic agent against the tissue by the jacket enhances transfer of the therapeutic  
30 agent into the tissue. The pressure is sufficient to allow release of the therapeutic agent without damaging the tissue. Similarly, movement of the heart can be used to drive release of the therapeutic agent from a bladder or patch.

In another embodiment, one or more therapeutic agents are delivered to the surface of the heart by injecting the agents into the myocardium through microneedles provided on the surface of the delivery source. Preferably, the delivery source comprises a bladder, and fine microneedles are connected to the bladder to  
5 provide a channel through which the therapeutic agents are transported into myocardium. In one embodiment, pneumatic pressure for infusing the therapeutic agent is provided by pressurizing the bladder with a catheter containing a proximal terminal connection routed to a location just under the patient's skin for easy access. Alternatively, energy transduced from diastolic filling of the heart can provide  
10 pressure for infusing the therapeutic agent. Diastolic filling of the heart applies pressure to the bladder, as the expanding heart encounters the restraining force of the jacket. This in turn causes release of the agent to target tissues.

As contemplated by the present invention, a therapeutic agent can be delivered to the heart or surrounding tissue of interest for a period of from several  
15 minutes, to several weeks.

The present invention provides improved capacity to deliver one or more therapeutic agents to one or more selected sites on the heart surface. The jacket of the invention encompasses all or a part of the heart, and all, or one or more selected areas of the jacket can be provided with a delivery source according to the invention.

20 In a particular aspect, the invention provides a delivery source that can be either bi-directional or uni-directional. Bi-directional release of the therapeutic agent is desirable, for example, when preventing adhesion between the heart and surrounding tissues. For example, when the target tissue is the heart, the delivery source can be adapted to release the therapeutic agent towards the heart only. In one  
25 embodiment, this uni-directional release can be accomplished by providing a coating containing the therapeutic agent on the jacket facing the heart only. Alternatively, when the target tissue is the tissue surrounding the heart, the delivery device can be adapted to release the therapeutic agent away from the heart, and thus towards the target tissues.

30 In one embodiment, the jacket material of the device can be fashioned in such a way that therapeutic agents retained in the delivery source are released only in the direction of the heart by modifying the porosity of the jacket material. In this

embodiment, the portion of the jacket facing or adjacent the heart has porosity large enough to allow the therapeutic agent to diffuse from the jacket and into the myocardium. The portion of the jacket facing away from the heart can be modified to be non-porous, or to contain pores of insufficient size to allow therapeutic agents to pass through. Alternatively, if the target tissue comprises tissue surrounding the heart, the jacket material can be modified such that therapeutic agent delivery is directed away from the heart, and towards the surrounding tissues. In yet another embodiment, an impermeable layer can be provided to create a barrier to prevent delivery of the therapeutic agent to a particular area of tissue. Delivery of the agent will, in this embodiment, occur in a direction opposite the barrier.

When the delivery source is provided in the form of a separate bladder or patch, the permeability of the delivery source can be adapted to allow selective release of the agent to target tissues, using the modification of porosity described above for the coating. Alternatively, an impermeable layer, as discussed above, can be provided in connection with the bladder or patch, to achieve directed delivery of the agent.

In one embodiment, the present invention provides for delivery to selected target areas of the heart and/or surrounding tissue. In this embodiment, delivery of the therapeutic agent is precisely controlled, so that only selected areas are exposed to the agent. This can be achieved, for example, by coating only a desired area of the jacket with the therapeutic agent, when the delivery source is provided in the form of a coating on the jacket. Alternatively, when the delivery source comprises a separate bladder or patch, the location of the delivery source can be controlled to expose only a limited target area to the agent or agents. For example, it may be desirable to apply an anti-fibrotic agent over areas of the heart including arteries, so that if it is necessary to access the arteries for future coronary artery repair, there would be no adhesion between the jacket and the heart.

Unlike solid drug delivery devices known in the art, the present invention provides a jacket of a knit biocompatible material that provides sustained, controlled release of a therapeutic agent to the heart or other target tissue. When the delivery source comprises a coating on the jacket, the jacket material provides a larger surface area for application of therapeutic agent(s), as well as a flexible device to



maintain intimate, non-shifting contact with the target tissue. The structure of the knit material allows the device to carry larger dosages of one or more therapeutic agents. Moreover, the jacket of the invention can be adapted to encompass the lower portion of the heart, the upper portion of the heart, or substantially the entire surface  
5 of the heart. Regardless of the surface area of the heart encompassed by the jacket of the invention, the delivery source of the device can be located at any desired target area, e.g., a specific surface artery of the heart or area of ischemia or necrosis.

It is understood that although the invention has been described in connection with heart applications, the methods and device described herein can be readily  
10 adapted for a variety of tissues in the body, using the teachings herein.

While a preferred embodiment of the present invention has been described, it should be understood that various changes, adaptations and modifications may be made therein without departing from the spirit of the invention and the scope of the appended claims.

What is claimed is:

1. A device for treating cardiac disease of a heart having an upper portion and a lower portion divided by an A-V groove, the device comprising:
  - 5       a. a jacket of flexible material defining a volume between an upper end and a lower end, the jacket adapted to be secured to the heart and adapted to be adjusted on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain expansion of the heart beyond a maximum adjusted volume during diastole and permit substantially unimpeded contraction of the heart during systole;  
10       and
  - b. a non-adherent material in association with the jacket.
2. The device according to claim 1 wherein the jacket comprises an elastic  
15   material.
3. The device according to claim 1 wherein the jacket comprises a biodegradable material.
- 20   4. The device according to claim 1, wherein the non-adherent material of the device is provided in the form of a lining that is placed between the jacket and a surface of the heart.
5. The device according to claim 1, wherein the non-adherent material of the device  
25   is provided in the form of one or more ribs extending from a base to an apex of the heart.
6. The device according to claim 1, wherein the non-adherent material is fabricated as an integral part of the jacket.
- 30   7. The device according to claim 1, wherein the non-adherent material is formed as a separate element from the jacket.

8. The device according to claim 1, wherein the non-adherent material is provided as a coating on the jacket.
- 5 9. The device according to claim 1 further comprising a delivery source for the delivery of one or more therapeutic agents to the surface of the heart.
- 10 10. The device according to claim 9 wherein the device provides localized delivery of the one or more therapeutic agents to a target area on the surface of the heart.
11. The device according to claim 9 wherein the therapeutic agent comprises a pharmacological agent.
- 15 12. The device according to claim 9 wherein the therapeutic agent comprises cellular material.
13. The device according to claim 9 wherein the delivery source comprises a coating on the jacket.
- 20 14. The device according to claim 9 wherein the delivery source comprises a separable element from the jacket.
- 25 15. The device according to claim 9 wherein the delivery source for the delivery of one or more therapeutic agents is provided at an area of the jacket that overlaps an area of the non-adherent material.
16. The device according to claim 15 wherein the non-adherent material is permeable to the therapeutic agent(s).
- 30 17. The device according to claim 9 wherein the delivery source for the delivery of one or more therapeutic agents is provided at an area of the jacket that is separate from an area of the non-adherent material.

18. A method for treating cardiac disease, the method comprising:

- a. surgically accessing the heart;
- b. applying a treatment device on the heart, the device comprising:
  - 5           1) a jacket of flexible material defining a volume between an upper end and a lower end, the jacket adapted to be secured to the heart and adapted to be adjusted on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain circumferential expansion of
  - 10           the heart beyond the maximum adjusted volume during diastole and permit substantially unimpeded contraction of the heart during systole; and
  - 2) a non-adherent material in association with the jacket;
- c. securing the treatment device to the heart; and
- 15           d. surgically closing access to the heart while leaving the treatment device on the
- heart.

19. The method according to claim 18, wherein the non-adherent material of the  
20 device is provided in the form of a lining that is placed between the jacket and a surface of the heart.

20. The method according to claim 18, wherein the non-adherent material of the  
device is provided in the form of one or more ribs extending from a base to an apex  
25 of the heart.

21. The method according to claim 18 wherein the non-adherent material is fabricated as an integral part of the jacket.

30 22. The method according to claim 18, wherein the non-adherent material is fabricated as a separate element from the jacket.

23. The method according to claim 18, wherein the treatment device further comprises a delivery source for delivery of one or more therapeutic agents to the surface of the heart.

5 24. The method according to claim 23, wherein the one or more therapeutic agents comprise one or more pharmacological agents.

25. The method according to claim 23 wherein the one or more therapeutic agents comprise cellular material.

10

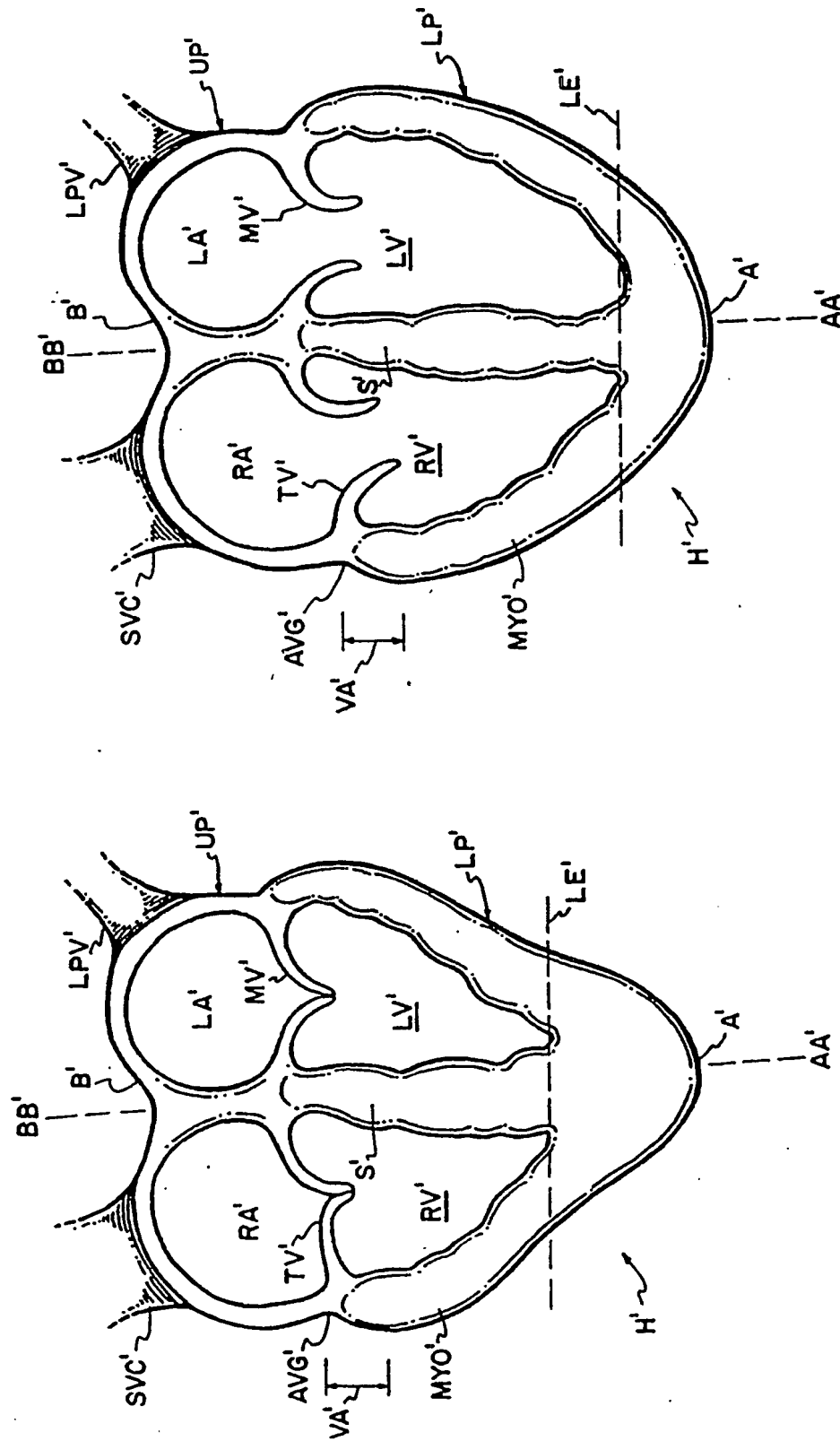


FIG. 1A

FIG. I

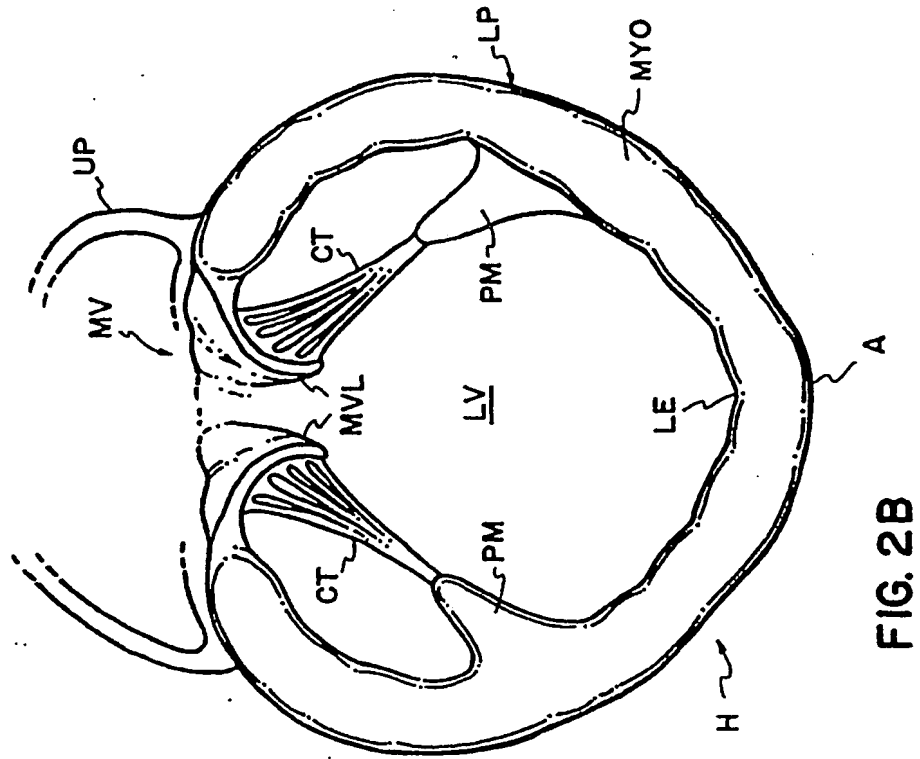


FIG. 2B

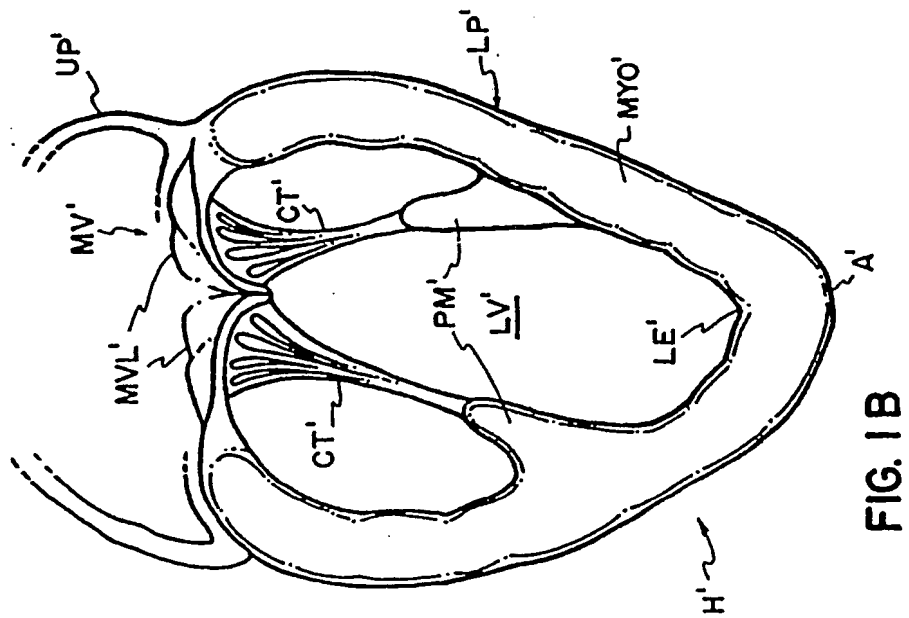


FIG. 1B

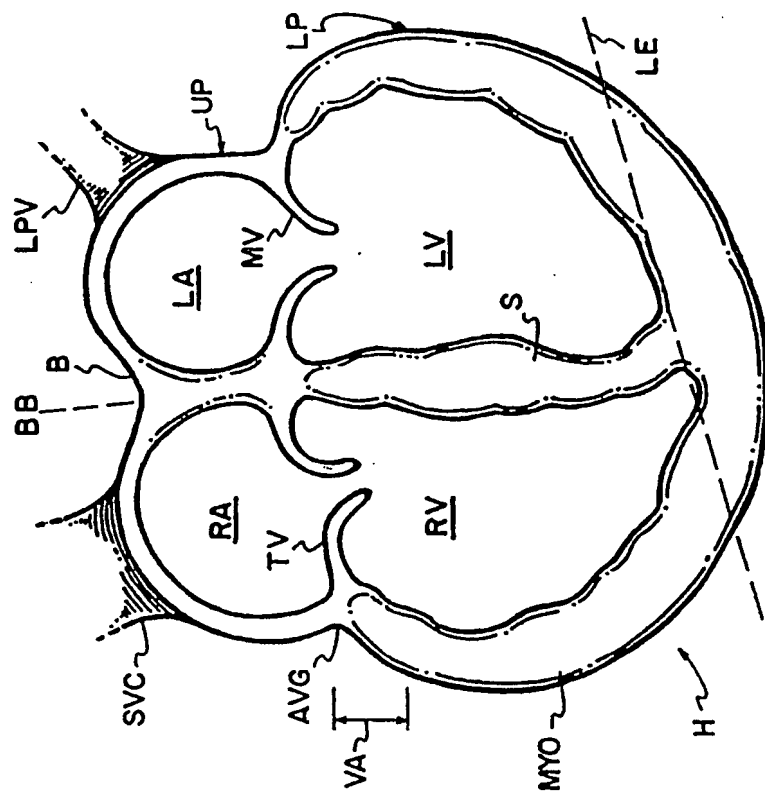


FIG. 2A

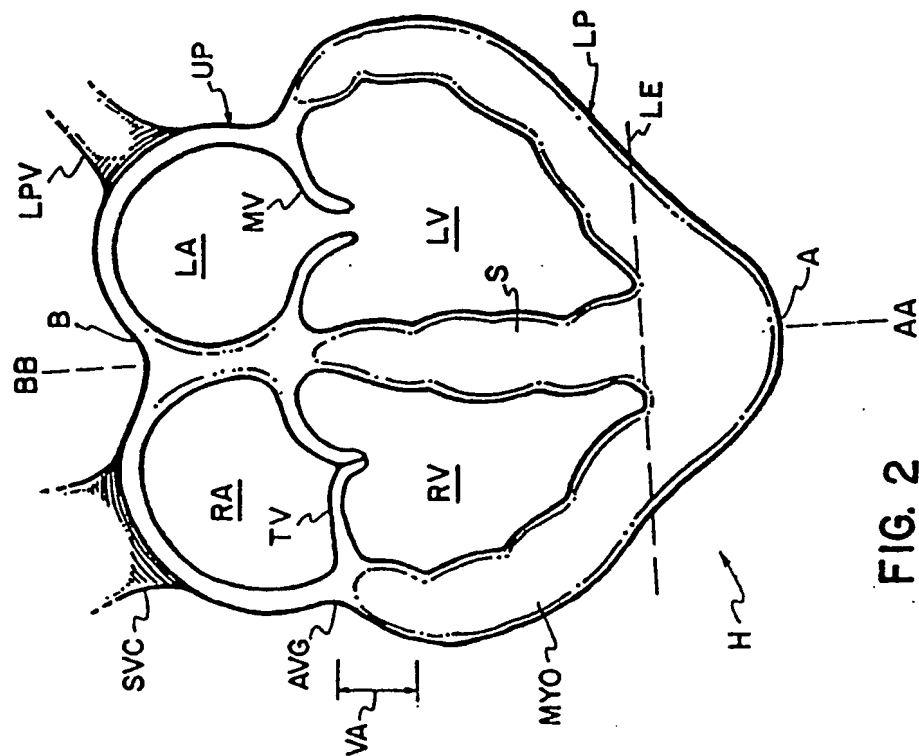


FIG. 2



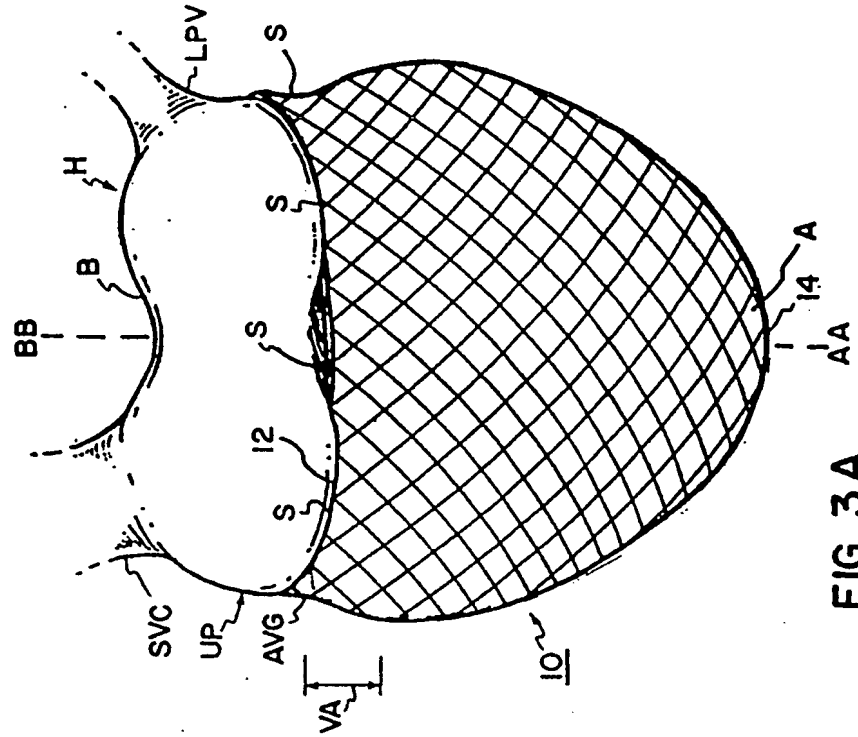


FIG. 3A

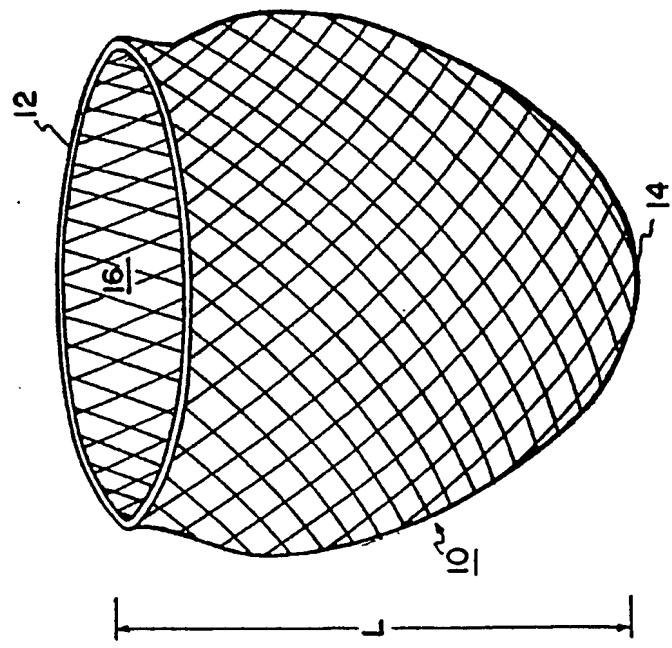
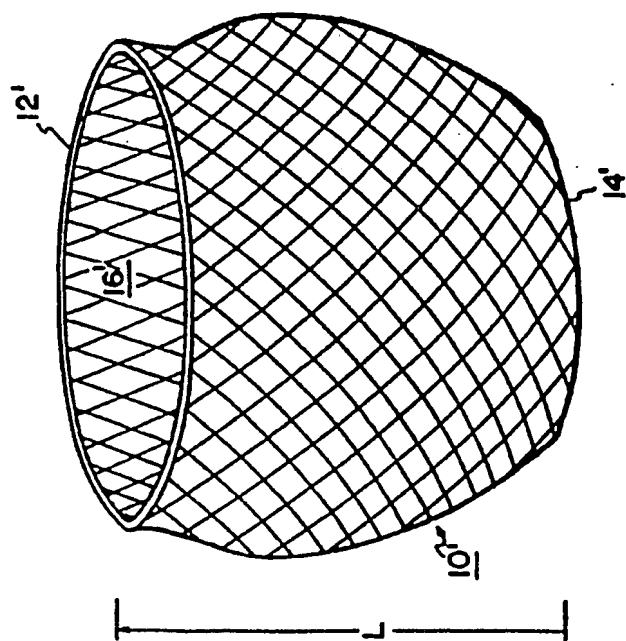
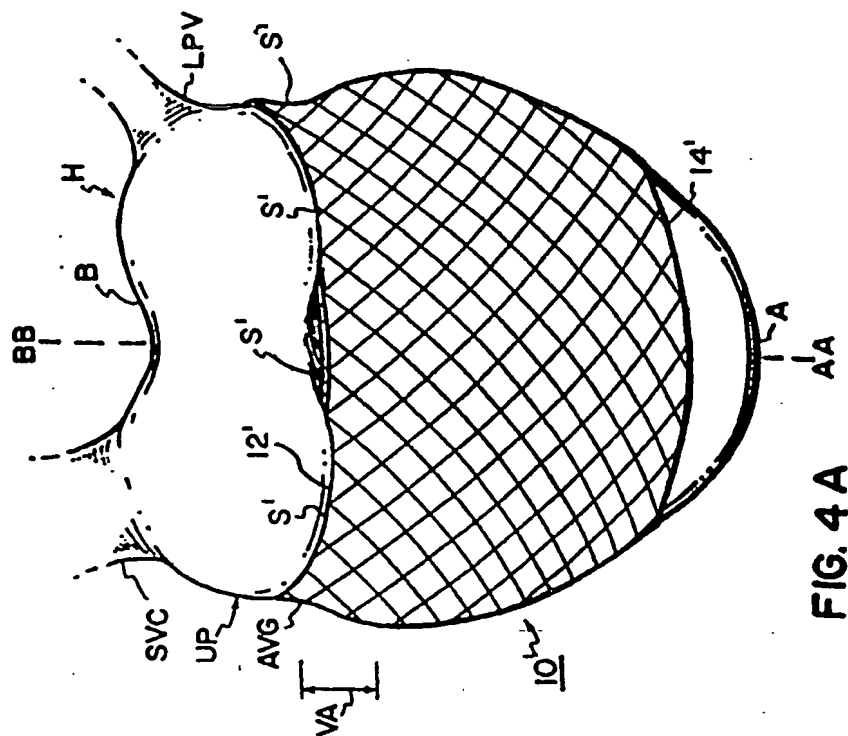
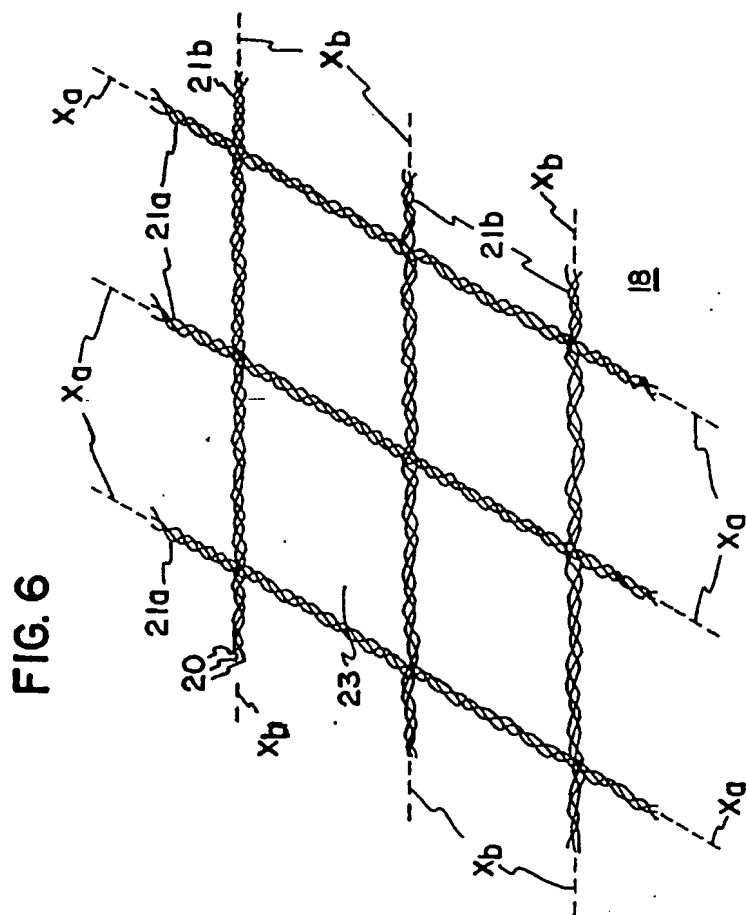


FIG. 3





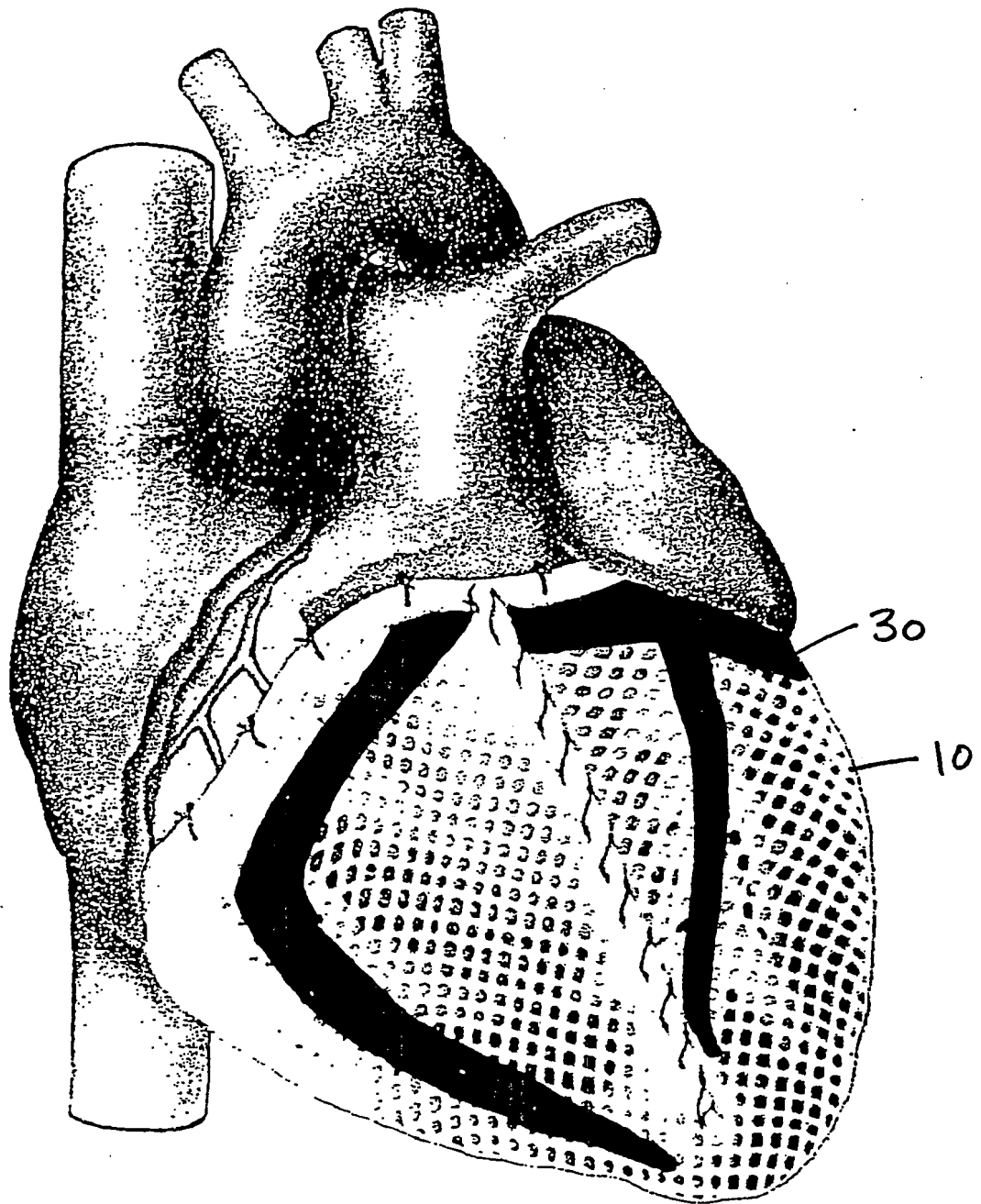


FIG. 8

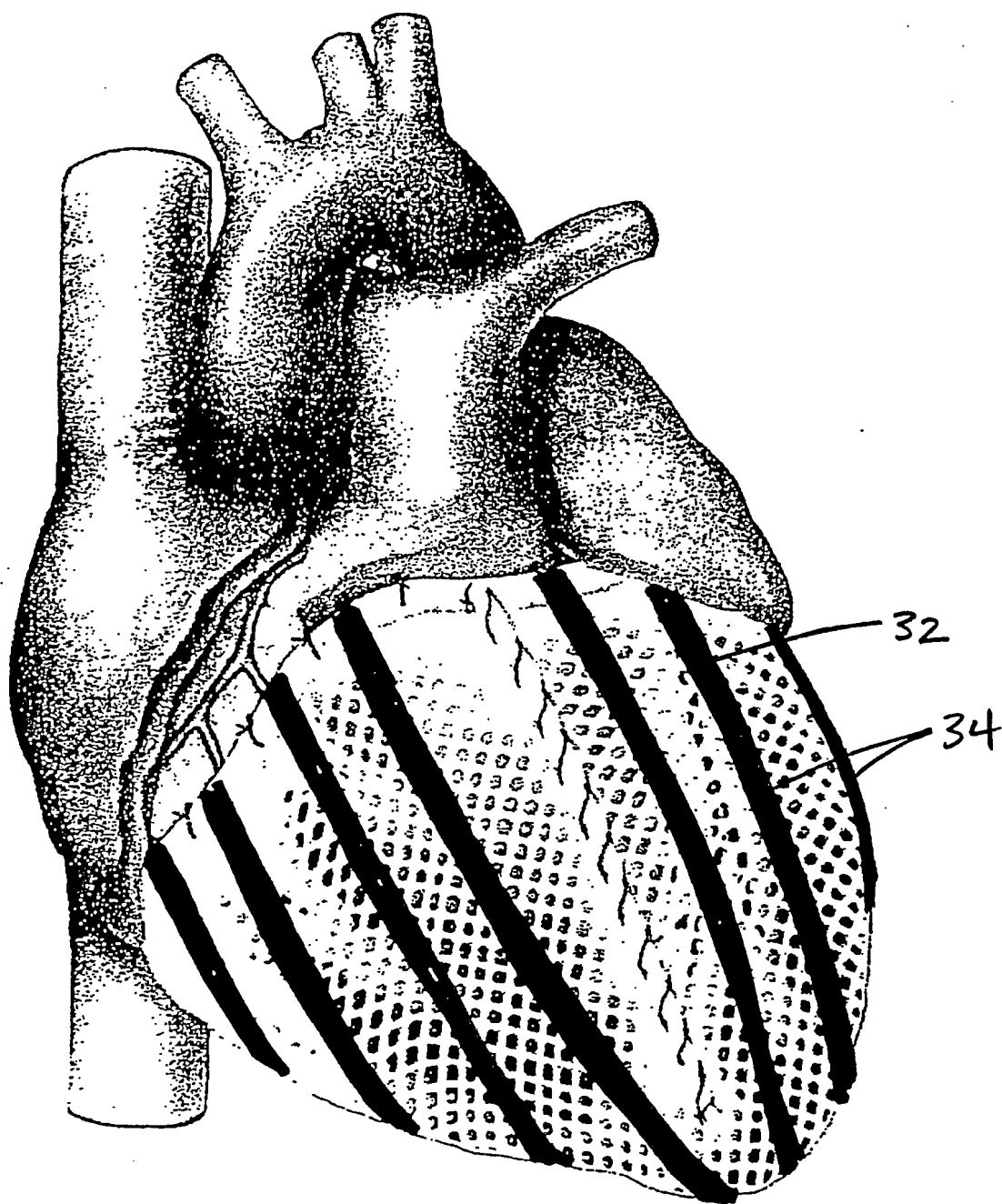


FIG. 9

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WO 01/95832 A2

(54) Title: **CARDIAC DISEASE TREATMENT AND DEVICE**

(57) Abstract: A device for treating cardiac disease of a heart having an upper portion and a lower portion divided by an A-V groove, the device including a jacket adapted to be secured to the heart, and a delivery source for the delivery of one or more therapeutic agents to the surface of the heart. The jacket is fabricated from a flexible material defining a volume between an upper and a lower end, the jacket being adapted to be adjusted on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain expansion of the heart beyond the maximum adjusted volume during diastole and permit substantially unimpeded contraction of the heart during systole. As a result of the flexible material, the jacket allows unimpeded diastolic filling of the heart. Also described is a method for treating cardiac disease including surgically accessing the heart, applying the treatment device of the invention, securing the treatment device to the heart, and surgically closing access to the heart while leaving the treatment device on the heart.

## CARDIAC DISEASE TREATMENT AND DEVICE

This application is being filed as a PCT application by ACORN  
CARDIOVASCULAR, INC., a United States national and resident, designating all  
5 countries except US.

### FIELD OF THE INVENTION

The present invention relates a device and method for treatment of cardiac  
disease and related cardiac complications. In particular, the present invention relates  
to a device for treating cardiac disease that includes a jacket that is adapted to be  
10 secured to the heart, and a delivery source for the delivery of a therapeutic agent to  
the surface of the heart.

### BACKGROUND OF THE INVENTION

Chronic or congestive heart disease is a progressive and debilitating illness.  
15 The disease is characterized by a progressive enlargement of the heart. Often, heart  
failure develops as a consequence of coronary atherosclerosis and myocardial  
infarction. After an infarction, the irreversibly injured myocardium is gradually  
replaced with fibrous scar tissue, since myocytes have limited ability to proliferate,  
and lost myocytes cannot regenerate. As myocytes are replaced with fibroblasts and  
20 collagen, changes in the mechanics of the heart lead to progressive onset of  
congestive heart failure.

As the heart enlarges, the heart is performing an increasing amount of work  
in order to pump blood with each heart beat. In time, the heart becomes so enlarged  
the heart cannot adequately supply blood. An afflicted patient is fatigued, unable to  
25 perform even simple exerting tasks and experiences pain and discomfort. Further, as  
the heart enlarges, the internal heart valves cannot adequately close. This impairs  
the function of the valves and further reduces the heart's ability to supply blood.

Causes of congestive heart disease are not fully known. In certain instances,  
congestive heart disease may result from viral infections. In such cases, the heart  
30 may enlarge to such an extent that the adverse consequences of heart enlargement  
continue after the viral infection has passed and the disease continues its  
progressively debilitating course.

Patients suffering from congestive heart disease are commonly grouped into four classes (i.e., NYHA Classes I, II, III and IV). In the early stages (e.g., Classes I and II), drug therapy is the commonly proscribed treatment. Drug therapy treats the symptoms of the disease and may slow the progression of the disease. Importantly, there is no cure for congestive heart disease. Even with drug therapy, the disease will progress. Further, the drugs may have adverse side effects, particularly when they are administered through the bloodstream.

Presently, the only permanent treatment for congestive heart disease is heart transplant. To qualify, a patient must be in the later stage of the disease (e.g., Classes III and IV with Class IV patients given priority for transplant). Such patients are extremely sick individuals. Class III patients have marked physical activity limitations and Class IV patients are symptomatic even at rest.

Due to the absence of effective intermediate treatment between drug therapy and heart transplant, Class III and IV patients will have suffered terribly before qualifying for heart transplant. Further, after such suffering, the available treatment is unsatisfactory. Heart transplant procedures are very risky, extremely invasive and expensive and only shortly extend a patient's life. For example, prior to transplant, a Class IV patient may have a life expectancy of 6 months to one-year. Heart transplant may improve the expectancy to about five years.

Unfortunately, not enough hearts are available for transplant to meet the needs of congestive heart disease patients. In the United States, in excess of 35,000 transplant candidates compete for only about 2,000 transplants per year. A transplant waiting list is about 8 – 12 months long on average and frequently a patient may have to wait about 1 – 2 years for a donor heart. While the availability of donor hearts has historically increased, the rate of increase is slowing dramatically. Even if the risks and expense of heart transplant could be tolerated, this treatment option is becoming increasingly unavailable. Further, many patient's do not qualify for heart transplant for failure to meet any one of a number of qualifying criteria.

Congestive heart failure has an enormous societal impact. In the United States alone, about five million people suffer from the disease (Classes I through IV combined). Alarming, congestive heart failure is one of the most rapidly



accelerating diseases (about 400,000 new patients in the United States each year). Economic costs of the disease have been estimated at \$38 billion annually.

Not surprising, substantial effort has been made to find alternative treatments for congestive heart disease and related complications. One alternative treatment is described in commonly assigned U.S. Patent No. 5,702,343 to Alferness dated December 30, 1997 teaches a jacket to constrain cardiac expansion during diastole. The present invention pertains to improvements to the invention disclosed in the '343 patent.

### SUMMARY OF THE INVENTION

10 The present invention provides a device and method for treating cardiac disease and related cardiac complications. According to the invention, the device comprises a jacket that is adapted to be secured to the heart, and a delivery source for the delivery of a therapeutic agent to the surface of the heart. Preferably, the device provides sustained, controlled release of one or more therapeutic agents while in intimate, non-shifting contact with the heart. In a preferred embodiment, application of the therapeutic agent can be localized so that the therapeutic agent is only delivered to one or more selected target areas of the heart and/or target areas surrounding the heart.

In one embodiment, a device for treating cardiac disease comprises a jacket of flexible material that is secured to the heart and conforms to an external geometry of the heart, and a delivery source for the delivery of a therapeutic agent to the surface of the heart. Preferably, the jacket is adapted to be adjusted on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain expansion of the heart beyond the maximum adjusted volume during diastole and permit substantially unimpeded contraction of the heart during systole. In one aspect, the therapeutic agent comprises one or more pharmacological agents, cellular material, or a combination thereof.

In another embodiment, methods for treating cardiac disease and related cardiac complications are described, the method comprising surgically accessing the heart; applying a treatment device on the heart, the device comprising a jacket of flexible material that is secured to the heart and conforms to an external geometry of

the heart, and a delivery source for the delivery of a therapeutic agent to the surface of the heart; securing the treatment device to the heart; and surgically closing access to the heart while leaving the treatment device on the heart.

In yet another embodiment, the invention provides a method for providing  
5 controlled and sustained administration of a therapeutic agent effective in treating cardiac disease and related cardiac complications, the method comprising surgically implanting a sustained therapeutic agent delivery system of the invention at a desired location on the heart.

10

### **BRIEF DESCRIPTION OF THE DRAWINGS**

Fig. 1 is a schematic cross-sectional view of a normal, healthy human heart shown during systole;

Fig. 1A is the view of Fig. 1 showing the heart during diastole;

Fig. 1B is a view of a left ventricle of a healthy heart as viewed from a  
15 septum and showing a mitral valve;

Fig. 2 is a schematic cross-sectional view of a diseased human heart shown during systole;

Fig. 2A is the view of Fig. 2 showing the heart during diastole;

Fig. 2B is the view of Fig. 1B showing a diseased heart;

20 Fig. 3 is a perspective view of a first embodiment of a cardiac constraint device according to the present invention;

Fig. 3A is a side elevation view of a diseased heart in diastole with the device of Fig. 3 in place;

25 Fig. 4 is a perspective view of a second embodiment of a cardiac constraint device according to the present invention;

Fig. 4A is a side elevation view of a diseased heart in diastole with the device of Fig. 4 in place;

Fig. 5 is a cross-sectional view of a device of the present invention overlying a myocardium and with the material of the device gathered for a snug fit;

30 Fig. 6 is an enlarged view of a knit construction of the device of the present invention in a rest state;

Fig. 7 is a schematic view of the material of Fig. 6; and

Fig. 8 is a perspective view of an embodiment of a cardiac reinforcement device according to the invention, including non-adherent biocompatible material placed between the jacket and the myocardium; and

Fig. 9 is a perspective view of an embodiment of a cardiac reinforcement device according to the invention, including non-adherent biocompatible material in the form of ribs in association with the jacket.

### DETAILED DESCRIPTION

The present invention provides devices and methods for treatment of cardiac conditions such as cardiomyopathy, valvular insufficiency, arrhythmias, and other cardiac complications. Generally, the invention is directed to a jacket that is secured to the heart and constrains expansion of the heart during diastole to a predetermined limit, and a delivery source for the delivery of a therapeutic agent to the surface of the heart.

The present invention provides advantages over known methods of treatment for cardiac disorders. Many known methods of drug treatment involve delivering the drugs to the site of action through the bloodstream. The amount of time required for these drugs to have the desired effect, and how long their effects last often depend upon several factors, including how quickly the drugs get into the bloodstream, how much of them gets into the bloodstream, how quickly they leave the bloodstream, how efficiently they are broken down (metabolized) by the liver, and how quickly they are eliminated by the kidneys and intestines. A drug may move slowly from the bloodstream into the body's tissues. Moreover, drugs penetrate different tissues at different speeds, depending upon their ability to cross membranes. In general, fat-soluble drugs can cross cell membranes more quickly than water-soluble drugs.

Intravenous administration of a drug may present adverse side effects when the systemic level of a drug exceeds a tolerable limit. Distribution of a drug may be further complicated when the drug is administered into the bloodstream. Once absorbed, most drugs do not spread out evenly through the body. Some drugs tend to stay within the watery tissues of the blood and muscles, while others concentrate in specific tissues such as the thyroid gland, liver, and kidneys. Additionally, some

drugs bind tightly to blood proteins, leaving the bloodstream very slowly, while others escape from the bloodstream quickly into other tissues. Some tissues build up such high levels of a drug that they serve as reservoirs of extra drug, thereby prolonging the drug's distribution. In fact, some drugs, such as those that  
5 accumulate in fatty tissues, leave these tissues slowly and consequently circulate in the bloodstream for some days after a person has stopped taking the drug.

In contrast, localized, targeted delivery of the drug can avoid undesirable systemic effects by eliminating circulation of the drug in areas of the body other than the target tissue.

10 It would be beneficial to be able to treat congestive heart disease or other related cardiac disorder with a drug while avoiding undesirable systemic effects such as drug-associated systemic toxic effects.

The present invention provides a combination of such advantages as controllability of therapeutic agent delivery (including duration of exposure to the  
15 agent, dosage, and size of the target area to be exposed to the agent), and contact between the therapeutic agent and the target surface that is intimate, long-term, and non-shifting. The present invention can target delivery of the therapeutic agent to a specific target area on or around the heart. If desired, the entire surface of the heart can be treated with the agent, or one or more specific areas of the heart can be  
20 treated. The ability to target the therapeutic agent as desired avoids adverse systemic effects of therapeutic agents.

The present invention maintains a controlled release of the therapeutic agent after implantation of the device. According to the present invention, the delivery source for delivery of a therapeutic agent to the surface of the heart is provided in  
25 non-shifting contact with the heart surface, allowing sustained treatment of a defined area of the heart. The present invention also provides a flexible device for delivery of the therapeutic agent, such that the device maintains intimate contact with the heart during delivery of the agent. This intimate, non-shifting contact with the heart achieves local delivery of a therapeutic agent that might otherwise be impossible or  
30 at least difficult to deliver as a result of such factors as poor blood flow to the target surface, for example, as a result of ischemia. Because the present invention delivers

the therapeutic agent directly to a localized target surface, lower amounts, but potentially higher localized concentrations, of the therapeutic agent can be delivered.

The invention is not limited to treatment of the heart. The device and method can be used to treat tissues surrounding the heart or other tissues of the body, as desired. The invention thus provides controlled release of a therapeutic agent to tissues of the body.

In one preferred embodiment, the mechanical energy of the heart drives drug delivery. In this embodiment, for example, the pressure of the heart against the jacket of the device controls release of the therapeutic agent from the delivery source of the device. In another preferred embodiment, the present invention can expose the target tissue to a combination of agents, when treatment with more than one type of agent is desired. For example, one or more anti-arrhythmic drugs and one or more desired antibiotics can be provided in connection with the device, when the physician determines that both the rhythm of the heart and potential infections are to be controlled.

With initial reference to Figs. 1 and 1A, a normal, healthy human heart H' is schematically shown in cross-section and will now be described in order to facilitate an understanding of the present invention. In Fig. 1, the heart H' is shown during systole (i.e., high left ventricular pressure). In Fig. 1A, the heart H' is shown during diastole (i.e., low left ventricular pressure).

The heart H' is a muscle having an outer wall or myocardium MYO' and an internal wall or septum S'. The myocardium MYO' and septum S' define four internal heart chambers including a right atrium RA', a left atrium LA', a right ventricle RV' and a left ventricle LV'. The heart H' has a length measured along a longitudinal axis AA' – BB' from an upper end or base B' to a lower end or apex A'.

The right and left atria RA', LA' reside in an upper portion UP' of the heart H' adjacent the base B'. The right and left ventricles RV', LV' reside in a lower portion LP' of the heart H' adjacent the apex A'. The ventricles RV', LV' terminate at ventricular lower extremities LE' adjacent the apex A' and spaced therefrom by the thickness of the myocardium MYO'.

Due to the compound curves of the upper and lower portions UP', LP', the

upper and lower portions UP', LP' meet at a circumferential groove commonly referred to as the A-V groove AVG'. Extending away from the upper portion UP' are a plurality of major blood vessels communicating with the chambers RA', RV', LA', LV'. For ease of illustration, only the superior vena cava SVC' and a left  
5 pulmonary vein LPV' are shown as being representative.

The heart H' contains valves to regulate blood flow between the chambers RA', RV', LA', LV' and between the chambers and the major vessels (e.g., the superior vena cava SVC' and a left pulmonary vein LPV'). For ease of illustration, not all of such valves are shown. Instead, only the tricuspid valve TV' between the  
10 right atrium RA' and right ventricle RV' and the mitral valve MV' between the left atrium LA' and left ventricle LV' are shown as being representative.

The valves are secured, in part, to the myocardium MYO' in a region of the lower portion LP' adjacent the A-V groove AVG' and referred to as the valvular annulus VA'. The valves TV' and MV' open and close through the beating cycle of  
15 the heart H.

Figs. 1 and 1A show a normal, healthy heart H' during systole and diastole, respectively. During systole (Fig. 1), the myocardium MYO' is contracting and the heart assumes a shape including a generally conical lower portion LP'. During diastole (Fig. 1A), the heart H' is expanding and the conical shape of the lower  
20 portion LP' bulges radially outwardly (relative to axis AA' - BB').

The motion of the heart H' and the variation in the shape of the heart H' during contraction and expansion is complex. The amount of motion varies considerably throughout the heart H'. The motion includes a component which is parallel to the axis AA' - BB' (conveniently referred to as longitudinal expansion or  
25 contraction). The motion also includes a component perpendicular to the axis AA'-BB' (conveniently referred to as circumferential expansion or contraction).

Having described a healthy heart H' during systole (Fig. 1) and diastole (Fig. 1A), comparison can now be made with a heart deformed by congestive heart disease. Such a heart H is shown in systole in Fig. 2 and in diastole in Fig. 2A. All  
30 elements of diseased heart H are labeled identically with similar elements of healthy heart H' except only for the omission of the apostrophe in order to distinguish diseased heart H from healthy heart H'.

Comparing Figs. 1 and 2 (showing hearts H' and H during systole), the lower portion LP of the diseased heart H has lost the tapered conical shape of the lower portion LP' of the healthy heart H'. Instead, the lower portion LP of the diseased heart H bulges outwardly between the apex A and the A-V groove AVG. So  
 5 deformed, the diseased heart H during systole (Fig. 2) resembles the healthy heart H' during diastole (Fig. 1A). During diastole (Fig. 2A), the deformation is even more extreme.

As a diseased heart H enlarges from the representation of Figs. 1 and 1A to that of Figs. 2 and 2A, the heart H becomes a progressively inefficient pump.  
 10 Therefore, the heart H requires more energy, with greater oxygen demand, to pump the same amount of blood. Continued progression of the disease results in the heart H being unable to supply adequate blood to the patient's body and the patient exhibits symptomatic insufficiency.

For ease of illustration, the progression of congestive heart disease has been  
 15 illustrated and described with reference to a progressive enlargement of the lower portion LP of the heart H. While such enlargement of the lower portion LP is most common and troublesome, enlargement of the upper portion UP may also occur.

In addition to cardiac insufficiency, the enlargement of the heart H can lead to valvular disorders. As the circumference of the valvular annulus VA increases,  
 20 the leaflets of the valves TV and MV may spread apart. After a certain amount of enlargement, the spreading may be so severe the leaflets cannot completely close (as illustrated by the mitral valve MV in Fig. 2A). Incomplete closure results in valvular regurgitation contributing to an additional degradation in cardiac performance. While circumferential enlargement of the valvular annulus VA may  
 25 contribute to valvular dysfunction as described, the separation of the valve leaflets is most commonly attributed to deformation of the geometry of the heart H. This is best described with reference to Figs. 1B and 2B.

Figs. 1B and 2B show a healthy and diseased heart, respectively, left ventricle LV', LV during systole as viewed from the septum (not shown in Figs. 1B  
 30 and 2B). In a healthy heart H', the leaflets MVL' of the mitral valve MV' are urged closed by left ventricular pressure. The papillary muscles PM', PM are connected to the heart wall MYO', MYO, near the lower ventricular extremities LE', LE. The

papillary muscles PM', PM pull on the leaflets MVL', MVL via connecting chordae tendineae CT', CT. Pull of the leaflets by the papillary muscles functions to prevent valve leakage in the normal heart by holding the valve leaflets in a closed position during systole. In the significantly diseased heart H, the leaflets of the mitral valve  
5 may not close sufficiently to prevent regurgitation of blood from the ventricle LV to the atrium during systole.

As shown in Fig. 1B, the geometry of the healthy heart H' is such that the myocardium MYO', papillary muscles PM' and chordae tendineae CT' cooperate to permit the mitral valve MV' to fully close. However, when the myocardium MYO  
10 bulges outwardly in the diseased heart H (Fig. 2B), the bulging results in displacement of the papillary muscles PM. This displacement acts to pull the leaflets MVL to a displaced position such that the mitral valve cannot fully close.

Having described the characteristics and problems of congestive heart disease, the treatment method and apparatus of the present invention will now be  
15 described.

The device of the present invention comprises a jacket adapted to be secured to the heart and a delivery source for delivery of one or more therapeutic agents to the heart. In general, a jacket of the invention is configured to surround the  
20 myocardium MYO. As used herein, "surround" means that the jacket provides reduced expansion of the heart wall at end diastole by applying constraining surfaces at least at diametrically opposing aspects of the heart. In some preferred embodiments disclosed herein, the diametrically opposed surfaces are interconnected, for example, by a continuous material that can substantially encircle  
25 the external surface of the heart. The jacket is also preferably fabricated from a flexible material to allow unrestricted filling of the heart during diastole.

With reference now to Figs. 3, 3A, 4 and 4A, the device of the present invention is shown as a jacket 10 of flexible, biologically compatible material. As used herein, "biologically compatible material" means material that is not  
30 biologically adverse such that the material will not cause adverse effects to surrounding tissues, such as rejection, infection, inflammation, and the like. Such material can be a biostable material such as a biostable polymer, or a biodegradable



material as discussed in more detail below.

The jacket 10 is an enclosed knit material having upper and lower ends 12, 14. The jacket 10, 10' defines an internal volume 16, 16' which is completely enclosed but for the open ends 12, 12' and 14'. In the embodiment of Fig. 3, lower  
5 end 14 is closed. In the embodiment of Fig. 4, lower end 14' is open. In both embodiments, upper ends 12, 12' are open. Alternatively, upper ends 12, 12' can be closed while allowing the SVC, LVC and other blood vessels to pass through the jacket material. Throughout this description, the embodiment of Fig. 3 will be discussed. Elements in common between the embodiments of Figs. 3 and 4 are  
10 numbered identically with the addition of an apostrophe to distinguish the second embodiment and such elements need not be separately discussed.

The jacket 10 is dimensioned with respect to a heart H to be treated. Specifically, the jacket 10 is sized for the heart H to be constrained within the volume 16. The jacket 10 can be slipped around the heart H. The jacket 10 has a  
15 length L between the upper and lower ends 12, 14 sufficient for the jacket 10 to constrain the lower portion LP. The upper end 12 of the jacket 10 extends at least to the valvular annulus VA and further extends to the lower portion LP to constrain at least the lower ventricular extremities LE.

The jacket of the invention can be provided in any suitable size and shape for  
20 application to the heart. In one embodiment for example, the jacket 10 is provided in a conical shape. As used herein, "conical" refers to a shape of the jacket wherein the diameter of the jacket decreases from the upper end 12, 12' towards the lower end 14, 14', to approximate the ellipsoid shape of the heart. In one embodiment, the size of the jacket 10 is predetermined, such that the jacket is fabricated in a conical  
25 shape prior to application to the heart. Alternatively, the shape of the jacket is adjusted at the time of placement of the device on the heart.

Since enlargement of the lower portion LP is most troublesome, in a preferred embodiment, the jacket 10 is sized so that the upper end 12 can reside in the A-V groove AVG. Where it is desired to constrain enlargement of the upper  
30 portion UP, the jacket 10 may be extended to cover the upper portion UP.

Sizing the jacket 10 for the upper end 12 to terminate at the A-V groove AVG may be desirable for a number of reasons. First, the groove AVG is a readily

identifiable anatomical feature to assist a surgeon in placing the jacket 10. By placing the upper end 12 in the A-V groove AVG, the surgeon is assured the jacket 10 will provide sufficient constraint at the valvular annulus VA. The A-V groove AVG and the major vessels act as natural stops for placement of the jacket 10 while  
5 assuring coverage of the valvular annulus VA. Using such features as natural stops is particularly beneficial in minimally invasive surgeries where a surgeon's vision may be obscured or limited.

When the parietal pericardium is opened, the lower portion LP is free of obstructions for applying the jacket 10 over the apex A. If, however, the parietal  
10 pericardium is intact, the diaphragmatic attachment to the parietal pericardium inhibits application of the jacket over the apex A of the heart. In this situation, the jacket can be opened along a line extending from the upper end 12' to the lower end 14' of jacket 10'. The jacket can then be applied around the pericardial surface of the heart and the opposing edges of the opened line secured together after being placed  
15 on the heart. Systems for securing the opposing edges are disclosed in, for example, U.S. Patent No. 5,702,343, the entire disclosure of which is incorporated herein by reference.

In the embodiment of Figs. 3 and 3A, the lower end 14 is closed and the length L is sized for the apex A of the heart H to be received within the lower end 14  
20 when the upper end 12 is placed at the A-V groove AVG. In the embodiment of Figs. 4 and 4A, the lower end 14' is open and the length L' is sized for the apex A of the heart H to protrude beyond the lower end 14' when the upper end 12' is placed at the A-V groove AVG. The length L' is sized so that the lower end 14' extends beyond the lower ventricular extremities LE such that in both of jackets 10, 10', the  
25 myocardium MYO surrounding the ventricles RV, LV is in direct opposition to material of the jacket 10, 10'. Such placement is desirable for the jacket 10, 10' to present a constraint against enlargement of the ventricular walls of the heart H.

After the jacket 10 is positioned on the heart H as described above, the jacket 10 is secured to the heart. Preferably, the jacket 10 is secured to the heart H through  
30 sutures or other suitable surgical attachment methods. The jacket 10 is sutured to the heart H at suture locations S circumferentially spaced along the upper end 12. While a surgeon may elect to add additional suture locations to prevent shifting of

the jacket 10 after placement, the number of such locations S is preferably limited so that the jacket 10 does not restrict contraction of the heart H during systole.

In another embodiment, the jacket is secured to the heart using a suitable bioadhesive. The bioadhesive can be used in connection with a jacket alone, or in  
5 combination with one or more therapeutic agents and/or a nonadherent material. As used herein, a "bioadhesive" means a material that adheres an element to a biological tissue, or two biological tissues to each other. Preferably, the bioadhesive is fabricated from a material that is biologically compatible and allows secure attachment to a tissue. According to the present invention, preferred bioadhesives  
10 attach the jacket 10 to the heart in a sufficient non-shifting manner and for a sufficient amount of time to allow the desired effects. The bioadhesive preferably secures the jacket sufficiently to avoid dislocation of the jacket as a result of the heart's natural movement. Preferred bioadhesives are thus somewhat flexible to accommodate movement of the heart or surrounding tissue.

15 Preferably, bioadhesives used in accordance with the invention do not cause undesired adverse effects, such as irritation, inflammation, infection, and the like, of tissues of the heart and/or in proximity thereto. Preferably, when the jacket is used in connection with a bioadhesive, suitable bioadhesives do not interfere with penetration of a therapeutic agent from the device into the myocardium. In one  
20 embodiment, areas of the device that include one or more bioadhesives are separate from areas that include one or more therapeutic agents. Alternatively, areas of the device that include one or more bioadhesives overlap areas that include one or more therapeutic agents. In this alternative embodiment, the bioadhesive is preferably permeable to the therapeutic agent, so that the bioadhesive does not interfere with  
25 release of the therapeutic agent to the surface of the heart. In yet another embodiment, the bioadhesive itself includes one or more therapeutic agents.

Preferred bioadhesives are fabricated from such materials as polyethylene glycol, fibrin, cyanoacrylate, or material comprising a combination of bovine serum albumin (BSA) and gluteraldehyde. Suitable polyethylene glycol-based materials  
30 are provided by Focal, Inc., under the product name Focal Seal™, and Cohesion Technologies, Inc. under the product name CoSeal™. Examples of fibrin-based materials are provided by Haemacure Corporation under the product name

Hemaseel™. Suitable material based in combining bovine serum albumin and gluteraldehyde are provided by Cryolife International, Inc.. Examples of cyanoacrylate-based materials are provided by Johnson & Johnson under product name Dermabond™. Other suitable bioadhesives known in the art could be substituted for the above materials, given the description herein.

To permit the jacket 10 to be easily placed on the heart H, the volume and shape of the jacket 10 are larger than the lower portion LP during diastole. So sized, the jacket 10 may be easily slipped around the heart H. Once placed, the jacket's volume and shape are adjusted for the jacket 10 to snugly conform to the external geometry of the heart H during diastole. Such sizing is easily accomplished due to the knit construction of the jacket 10. For example, excess material of the jacket 10 can be gathered and sutured S" (Fig. 5) to reduce the volume of the jacket 10 and conform the jacket 10 to the shape of the heart H during diastole. Such shape represents a maximum adjusted volume. The jacket 10 constrains enlargement of the heart H beyond the maximum adjusted volume while preventing restricted contraction of the heart H during systole. Preferably, the flexible material of the jacket allows unrestricted filling of the heart during diastole. As an alternative to gathering of Fig. 5, the jacket 10 can be provided with other ways of adjusting volume. For example, as disclosed in U.S. Patent No. 5,702,343, the jacket can be provided with a slot. The edges of the slot can be drawn together to reduce the volume of the jacket.

The volume of the jacket can be adjusted prior to, during, or after application of the device to the heart. In one embodiment, the heart is treated with a therapeutic agent, such as a drug, to decrease the size of the heart prior to application of the jacket. In this embodiment, the therapeutic agent acts to reduce the overall size of the heart prior to surgery, and the jacket is thereafter applied to the reduced heart. In another embodiment, the size of the heart is reduced by placement of the device on the heart, and sizing of the device to urge the heart to a reduced size. More preferably, the heart size can be reduced at the time of jacket placement through drugs, for example dobutamine, dopamine or epinephrine or any other positive inotropic agents. Alternatively, surgical procedure can be used to reduce the heart size. The jacket of the present invention is then snugly placed on the reduced sized

heart and prevents or reduces enlargement beyond the reduced size.

The jacket 10 is adjusted to a snug fit on the heart H during diastole. Care is taken to avoid tightening the jacket 10 too much such that cardiac function is impaired. During diastole, the left ventricle LV fills with blood. If the jacket 10 is too tight, the left ventricle LV cannot adequately expand and left ventricular pressure will rise. During the fitting of the jacket 10, the surgeon can monitor left ventricular pressure. For example, a well-known technique for monitoring so-called pulmonary wedge pressure uses a catheter placed in the pulmonary artery. The wedge pressure provides an indication of filling pressure in the left atrium LA and left ventricle LV. While minor increases in pressure (e.g., 2 – 3 mm Hg) can be tolerated, the jacket 10 is snugly fit on the heart H but not so tight as to cause a significant increase in left ventricular pressure during diastole.

The jacket 10 is constructed from a knit, biocompatible material. The knit 18 is illustrated in Fig. 6. Preferably, the knit is a so-called "Atlas knit" well known in the fabric industry. The Atlas knit is described in Paling, Warp Knitting Technology, p. 111, Columbine Press (Publishers) Ltd., Buxton, Great Britain (1970).

The Atlas knit is a knit of fibers 20 having directional expansion properties. More specifically, the knit 18, although formed of generally inelastic fibers 20, permits a construction of a flexible fabric at least slightly expandable beyond a rest state. Fig. 6 illustrates the knit 18 in a rest state. The fibers 20 of the fabric 18 are woven into two sets of fiber strands 21a, 21b having longitudinal axes  $X_a$  and  $X_b$ . The strands 21a, 21b are interwoven to form the fabric 18 with strands 21a generally parallel and spaced-apart and with strands 21b generally parallel and spaced-apart.

For ease of illustration, fabric 18 is schematically shown in Fig. 7 with the axis of the strands 21a, 21b only being shown. The strands 21a, 21b are interwoven with the axes  $X_a$  and  $X_b$  defining a diamond-shaped open cell 23 having diagonal axes  $A_m$ . In a preferred embodiment, the axes  $A_m$  are 5 mm in length when the fabric 18 is at rest and not stretched. The fabric 18 can stretch in response to a force. For any given force, the fabric 18 stretches most when the force is applied parallel to the diagonal axes  $A_m$ . The fabric 18 stretches least when the force is applied parallel to the strand axes  $X_a$  and  $X_b$ . The jacket 10 is constructed for the material of the knit to

be directionally aligned for a diagonal axis  $A_m$  to be parallel to the heart's longitudinal axis AA-BB.

While the jacket 10 is expandable due to the above described knit pattern, the fibers 20 of the knit 18 are preferably non-expandable. While all materials expand at least a small amount, the fibers 20 are preferably formed of a material with a low modulus of elasticity. In response to the low pressures in the heart H during diastole, the fibers 20 are essentially non-elastic. In a preferred embodiment, the fibers are 70 Denier polyester. While polyester is presently preferred, other suitable materials include polytetrafluoroethylene (PTFE), polypropylene, stainless steel, and the like. Alternatively, the fibers of the jacket are fabricated from a suitable biodegradable material or blends thereof, as described herein.

The knit material has numerous advantages. Such a material is flexible to permit unrestricted movement of the heart H (other than the desired constraint on cardiac dilation). The material is open, defining a plurality of interstitial spaces for fluid permeability as well as minimizing the amount of surface area of direct contact between the heart H and the material of the jacket 10 (thereby minimizing areas of irritation or abrasion) to minimize fibrosis and scar tissue.

The open areas of the knit construction also allow for electrical connection between the heart and surrounding tissue for passage of electrical current to and from the heart. For example, although the knit material is an electrical insulator, the open knit construction is sufficiently electrically permeable to permit the use of trans-chest defibrillation of the heart. Also, the open, flexible construction permits passage of electrical elements (e.g., pacer leads) through the jacket. Additionally, the open construction permits other procedures, e.g., coronary bypass, to be performed without removal of the jacket.

In one preferred embodiment, the interstitial spaces of the knit construction contain the therapeutic agent of the present invention. For example, in one embodiment, the interstitial spaces are filled with a biodegradable space fill material comprising a biologically compatible and/or biodegradable polymer matrix containing the therapeutic agent, as discussed in more detail below.

A large open area for cells 23 is desirable to minimize the amount of surface area of the heart H in contact with the material of the jacket 10 (thereby reducing

fibrosis). However, if the cell area 23 is too large, localized aneurysm can form. Also, a strand 21a, 21b can overlay a coronary vessel with sufficient force to partially block the vessel. A smaller cell size increases the number of strands thereby decreasing the restricting force per strand. In a preferred embodiment, the cell area CA of cells in a particular row directly correlates with a cross-sectional circumferential dimension of the heart that the row of cells surrounds relative to other cross-sectional circumferential dimensions. That is, the greater the cross-sectional circumferential dimension, the greater the area of the cells in the row of cells directly overlying that cross-sectional circumferential dimension. By "correlating" cell area with cross-sectional circumferential dimension of the heart, the cell area is determined as a function of the cross-sectional circumferential dimension of the heart. The cell area is determined so that when the weave material is applied to the heart or is shaped into a jacket and applied to the heart, each cell can widen sufficiently to provide desirable cardiac constraint. Thus, the cell area will be smaller for cells in a row applied over a region of the heart that has a smaller cross-sectional circumferential dimension than the cell area of cells in a row applied over a region of the heart having a larger cross-sectional circumferential dimension. The appropriate maximum cell area may be, for example, 1 to 100 mm<sup>2</sup>, typically 3 to 9 mm<sup>2</sup>. The maximum cell area is the area of a cell 23 after the material of the jacket 10 is fully stretched and adjusted to the maximum adjusted volume on the heart H as previously described.

The fabric 18 is preferably tear and run resistant. In the event of a material defect or inadvertent tear, such a defect or tear is restricted from propagation by reason of the knit construction.

In an alternative embodiment, the jacket is fabricated from an elastic material. A biologically compatible material suitable for a device of the invention generally has a lower compliance than the heart wall. Even though the biologically compatible material is less compliant than the heart wall, some limited expansion of an elastic biologically compatible material can occur during cardiac filling. Suitable elastic materials for jacket fabrication include, for example, polyurethane, silicone, and the like.

Regardless if the biologically compatible material is elastic or non-elastic,

advantageous to a device according to the present invention is cardiac reinforcement which is provided during diastole. Moreover, a device as disclosed herein does not provide cardiac assistance through active pumping of the heart.

A device and method to treat cardiac disease have been disclosed in U.S.

- 5 Patent No. 5,702,343 (commonly assigned to the assignee of the present invention, and the disclosure of which is incorporated herein by reference). The jacket 10 constrains further undesirable enlargement of the heart while not impeding other motion of the heart H. With the benefits of the present teachings, numerous modifications are possible. For example, the jacket 10 need not be directly applied
- 10 to the epicardium (i.e., outer surface of the myocardium) but could be placed over the parietal pericardium. Further, an anti-fibrosis lining (such as a PTFE, polyethylene glycol, polyethylene oxide, or other polymer coating on the fibers of the knit) could be used with the jacket 10, for example, between the heart and the jacket, or applied on the outer surface of the jacket (away from the heart).
- 15 Alternatively, the fibers 20 can be coated with PTFE.

- In one embodiment, a non-adherent material is provided in connection with the jacket 10 of the invention, to prevent unwanted fibrosis as a result of the presence of the jacket on the surface of the heart. As used herein, "non-adherent material" means a material that is biocompatible and does not adhere to surfaces of
- 20 organs, such as the epicardial surface of the heart. The material can be preformed in a manner similar to the jacket of the invention, as described above. In one embodiment, the non-adherent material is fabricated as part of the jacket of the invention. Alternatively, the non-adherent material is fabricated as a separate element of the invention, and is positioned between the jacket of the invention and
- 25 the epicardial surface of the heart. The non-adherent material facilitates removal of the jacket, which can become difficult when the jacket has been in place on the heart for a long period of time.

- The non-adherent material can be adapted to cover any desired surface of the heart, such as the entire surface of the heart, or selected areas of the heart only. In
- 30 one embodiment, the material can be fabricated to line the entire jacket, thus covering the entire epicardial surface of the heart that would otherwise be in contact with the jacket.



In another embodiment, the non-adherent material is placed on the outer surface of the jacket; that is, the surface of the jacket facing away from the heart. In this embodiment, the non-adherent material prevents unwanted fibrosis of surrounding tissues. Alternatively, the non-adherent material can be configured to  
5 be a hydrogel material that fills interstitial spaces of the jacket. It will be apparent to one of skill in the art that the non-adherent material can be configured to prevent undesirable fibrosis or other damage to any target tissue.

Removal of the jacket at selected sites may be required to access the coronary arteries in order to form an anastomotic site for coronary artery bypass in  
10 patients who received the device of the invention but subsequently develop coronary artery disease requiring bypass. Placement of non-adherent material at these selected sites facilitates removal of the jacket and access to these arteries. In one embodiment shown in Figure 8, the non-adherent material 30 is placed at strategic sites between the jacket 10 and the epicardial surface of the heart, to allow access to  
15 the coronary vessels. For example, the non-adherent material is placed to cover only the epicardial course of the major coronary arteries. This will allow a surgeon to remove part of the jacket if coronary artery bypass surgery is deemed necessary in a patient who received the device of the invention in the past.

Alternatively, the non-adherent material is placed at strategic base-to-apex  
20 locations to allow relief of constriction. In one embodiment shown in Figure 9, the non-adherent material 32 forms ribs 34 that course from base to apex of the heart. Preferably, the ribs are provided a finite distance apart along the device. This embodiment is desirable should the jacket cause constriction of the heart. The ribs allow the surgeon to score the jacket at the rib sites in the event a patient develops a  
25 constrictive or restrictive pattern as a result of the jacket. Relief of constriction is desirable in certain patients. For example, constrictive physiology may occur in some patients as a result of the presence of the jacket and pressure of the heart during diastole. This may in turn require removal of the jacket.

The non-adherent material is fabricated from any suitable material that  
30 provides the desired properties. In one embodiment, the non-adherent material is fabricated from the same material used to fabricate the jacket 10, for example, polyesters, PTFE, polypropylene, polyurethane, silicone, and the like. In yet another

embodiment, the non-adherent material is fabricated from a different material than the jacket 10. Another example of suitable non-adherent material is available commercially under the brand name GORE-TEXTM. In yet another embodiment, the non-adherent material is fabricated from a hydrogel, as described herein. The non-adherent material can be flexible or rigid, depending upon the desired application. Given the present teaching, one of skill in the art can select a suitable non-adherent material.

The non-adherent material is provided, in one embodiment, as a separate element of the device. For example, the non-adherent material can be provided as a separate lining that is placed between the jacket and the surface of the heart, or on the outside surface of the jacket, facing away from the heart. In yet another embodiment, the non-adherent material of the invention is provided as a coating on the jacket of the device.

The device of the invention can include non-adherent material and can optionally further include antifibrotic agents, if desired. Placement of the non-adherent material, when provided as a separate element of the device, is accomplished at any suitable time during application of the jacket, for example, prior to, during, or after placement of the jacket on the heart. When provided as a separate element of the device, the non-adherent material is held in place on the heart surface by the jacket 10. In this embodiment, the snug fit of the jacket 10 is sufficient to maintain the desired location of the non-adherent material on the heart.

Alternatively, the non-adherent material is attached to the jacket 10. In this alternative embodiment, attachment of the non-adherent material to the jacket, and the attachment of the jacket 10 to the heart (as discussed *supra*) maintains placement of the non-adherent material. Securement of the non-adherent material to the jacket can be accomplished using any suitable means, such as, for example, sutures, staples, bioadhesives, or the like. Given the description herein, one of skill in the art can readily choose suitable methods for securing the non-adherent material to the jacket.

The non-adherent material can be fabricated to be permeable to therapeutic agents, so that the material does not interfere with delivery of the agent(s) to the heart. Alternatively, the non-adherent material is impermeable to therapeutic

agent(s), for example, when there is no concern with interference of delivery of the therapeutic agent(s), such as when the location of the non-adherent material is separate from the location of any therapeutic agents included in the device.

5 The jacket 10 is low-cost, easy to place and secure, and is amendable to use in minimally invasive procedures. The thin, flexible fabric 18 permits the jacket 10 to be collapsed and passed through a small diameter tube in a minimally invasive procedure.

10 The jacket 10 can be used in early stages of congestive heart failure, such as myocardial infarction or congestive heart failure, or late stages, such as chronic dilated cardiomyopathy. For patients facing cardiac enlargement due to viral infection, the jacket 10 permits constraint of the heart H for a sufficient time to permit the viral infection to pass. In addition to preventing further heart enlargement, the jacket 10 treats valvular disorders by constraining circumferential enlargement of the valvular annulus and deformation of the ventricular walls.

15 The jacket 10, including the knit construction, freely permits longitudinal and circumferential contraction of the heart H (necessary for heart function). Unlike a solid wrap (such as a muscle wrap in a cardiomyoplasty procedure), the fabric 18 does not impede cardiac contraction. Further, the jacket permits unrestricted diastolic filling of the heart. The jacket prevents overstressing or stretching of the ventricle at the end of diastole. After fitting, the jacket 10 is inelastic to prevent  
20 further heart enlargement while permitting unrestricted inward movement of the ventricular walls. The open cell structure permits access to coronary vessels for bypass procedures subsequent to placement of the jacket 10. Also, in cardiomyoplasty, the latissimus dorsi muscle has a variable and large thickness  
25 (ranging from about 1 mm to 1 cm). In contrast, the material of the jacket 10 is uniformly thin (less than 1 mm thick). The thin wall construction thus reduces the risk of fibrosis and minimizes interference with cardiac contractile function.

Animal test studies on the jacket of the invention show the efficacy of the jacket of the present invention. Test animals were provided with the device 10 of  
30 Fig. 3. The animals' hearts were rapidly paced to induce heart failure. After six weeks, animals without the device experienced significant heart enlargement while those with the device experienced no significant enlargement. Further, animals with

the device had significantly reduced mitral valve regurgitation and had improved contractability as measured by ejection fraction.

The jacket described above is used in connection with a delivery source for the delivery of a therapeutic agent to the surface of the heart. As used herein, a  
5 “therapeutic agent” is an agent that assists in the treatment, cure, relief or prevention of disease or disorders of the heart or surrounding tissue. Therapeutic agents function by affecting the structure or function of the tissue treated, to have the desired effect.

The present invention provides a device and method for localized, targeted  
10 delivery of a therapeutic agent to a target area of the heart and/or of surrounding tissues. As used herein, “target,” “target area” and “target tissue” refer to a selected site of the heart, or of tissues surrounding the heart, intended to be treated using the present invention. As contemplated in the present invention, the target tissue can comprise any desired area to be treated with a method or device of the invention,  
15 including, for example, a specific area of the heart (such as an area of ischemia or necrosis, or one or more diseased or damaged arteries), the entire surface of the heart, or selected tissues surrounding the heart (such as the lung or pericardium). Further, after delivery to the surface of the target tissue, such as the heart, the therapeutic agent can penetrate the tissue surface and thereby act below the surface  
20 of the tissue.

As contemplated in the present invention, therapeutic agents include one or more pharmacological agents, cellular material, and/or combinations thereof. While the present application provides examples of suitable therapeutic agents, the disclosure hereof should not be interpreted to be so limited. The discussion of  
25 particular exemplary therapeutic agents herein is not meant to be limiting; rather, the disclosure should be interpreted to encompass suitable therapeutic agents within the scope of the invention.

Suitable pharmacological agents include chemicals or pharmacological compounds that affect the target tissue, such as the heart and/or surrounding tissues,  
30 and its processes. Examples of suitable pharmacological agents include anti-arrhythmic drugs, thrombolytic agents, anti-restenotic agents, anti-inflammatory or anti-fibrotic agents, anti-apoptotic agents, antibiotics, neurohormone inhibitors,

antineurohormone agonists, leukocyte inhibitory factor antagonists, glycoprotein 130 antagonists, anti-immune rejection agents, inhibitors of matrix metalloproteinases, agents that prevent calcification, agents that increase intracellular calcium without activating  $\beta$ -adrenergic receptors, metabolic factors, nucleic acid molecules, and other comparable agents capable of treating, curing, relieving or preventing disease or disorders in target tissues.

As contemplated by the present invention, anti-arrhythmic drugs are compounds that act to inhibit arrhythmia (that is, abnormal cardiac rhythm) and stabilize normal sinus rhythm to the heart. Examples of anti-arrhythmic drugs include those classified as type I (such as lidocaine, procainamide, encainide, flecainide), type II (for example,  $\beta$ -adrenergic blocking agents such as norepinephrine, epinephrine, isoproterenol, propranolol, dobutamine), and type III (such as ibutilide and sotalol), as well as quinidine, phenytoin, angiotensin converting enzyme (ACE) inhibitors, nitroglycerin, hydralazine, captopril, and calcium channel blockers such as verapamil, nifedipine, and diltiazem.

Thrombolytic agents are compounds that act to dissolve or split up clots in the body. Examples of suitable thrombolytic agents include streptokinase, urokinase, tissue plasminogen activator (TPA), and the like.

In another embodiment, the therapeutic agent of the present invention comprises one or more anti-restenotic agents. As used herein, anti-restenotic agents are agents that inhibit restenosis (i.e., cell proliferation) and/or extracellular matrix synthesis at the level of atherosclerotic plaque, of coronary arteries following percutaneous transluminal coronary angioplasty, or vascular grafts following coronary artery bypass grafting procedures. Examples of suitable anti-restenotic agents include anti-thrombotic agents (such as heparin and ReoPro), and radionuclide emitters, and the like.

Alternatively, the therapeutic agent of the present invention comprises one or more anti-inflammatory or anti-fibrotic agents. Such anti-inflammatory or anti-fibrotic agents are agents that inhibit scar formation associated with aberrant fibrosis and prevent formation of epicardial fibrosis, which could interfere with diffusion of other agents from the device of the present invention to the target tissue and could increase resistance to electric current flow, thus requiring a pacemaker to deliver

more voltage. Examples of suitable anti-inflammatory or anti-fibrotic agents include steroids, such as dexamethasone and the like, and lathrogenic agents such as penicillamine, n-acetyl-cysteine,  $\beta$ -aminopropionitrile, and the like.

In another embodiment, the therapeutic agent is provided in the form of a metabolic effector. As used herein, a metabolic effector represents a biologically active molecule that is capable of altering activity in a metabolic pathway. Thus, a metabolic effector is able to alter biological response elicited by intermediates, or final products of a metabolic pathway. Such effectors may be enzymes, enzyme inhibitors or stimulators, neurohormones, hormones, and the like. Examples include natural and pharmaceutical agents intended to serve as antagonists or agonists, with specific binding activity to enzymes involved in neurohormone metabolism, or cell membrane-bound receptors of such neurohormones. Among these metabolic effectors are ACE inhibitors, which inhibit angiotensin converting enzyme and metabolic conversion of angiotensin I to angiotensin II, thiorphan, which inhibits neutral endoprotease and prevents metabolic breakdown of atrial natriuretic peptide, spironolactone,  $\beta$ -blockers, and losartan. These latter three effectors are antagonists of aldosterone, catecholamines (such as norepinephrine), and angiotensin II, respectively, and thus inhibit receptor binding, and biological response normally elicited by these natural metabolites.

Alternatively, the therapeutic agent can be provided in the form of a therapeutic gene that functions to assist in the treatment, cure, relief or prevention of disease or disorders of the heart or surrounding tissue. As used herein, a "therapeutic gene" is a segment of nucleic acid that specifies a particular protein or polypeptide chain that, when expressed, provides a therapeutic effect. Many such therapeutic genes are known in the art to provide beneficial effects in the treatment of cardiac disease or disorders. For example, suitable therapeutic genes function to prevent restenosis, promote angiogenesis, modulate pathways of electrical conductance to control cardiac arrhythmias, enhance the wound healing process (for example, using such growth factors as TGF- $\beta$ ), or express thrombolytic agents such as tissue plasminogen activator (TPA) or urokinase.

In this embodiment, the therapeutic agent comprises one or more gene agents, such as naked gene plasmids, oligonucleotides, ribozymes, and viral vectors

containing genes encoding specific transgene products. Such gene agents provide mechanisms for introducing genes into the target area, to promote expression of a transgene product.

When provided in the form of nucleic acid, the therapeutic agent can be  
5 provided through a delivery system, such as liposomes, microspheres, nanospheres, and polymer matrices, or may be provided as naked nucleic acid. When provided with a polymer matrix, the nucleic acid can be either entrapped or dispersed into the polymer matrix or adsorbed onto the surface. Polymers can be provided as biodegradable materials such as polyesters or polyanhydrides or blends thereof;  
10 nonbiodegradable materials such as ethylene vinyl acetate copolymers; or natural materials such as collagen or gelatin.

Suitable pharmacological agents can be surface-acting or can penetrate the myocardium. For example, small molecule compounds are capable of penetrating the myocardium to act beneath the surface of the heart. Examples of small molecule  
15 compounds that are capable of penetrating the MYO include anti-arrhythmic agents, lathrogenic agents such as penicillamine, N-acetyl-L-cysteine, and 3-aminopropionitrile fumarate, and the like.

When the therapeutic agent comprises a pharmacological agent, the agent can be provided with any suitable carrier diluent, filler, binder or other excipient,  
20 depending upon the composition of the delivery source and the dosage desired, for delivery of the agent to the target tissue. By "carrier" is meant a pharmaceutically acceptable carrier that is conventionally used in the art to facilitate the storage, administration, and/or healing effect of the agent. A carrier may also reduce any undesirable side effects of the agent. A suitable carrier should be stable, i.e.,  
25 incapable of reacting with other ingredients of the formulation. It should not produce local adverse effects in recipients at the dosages and concentrations employed for treatment. Such carriers are generally known in the art. See Remington's Pharmaceutical Sciences, 16<sup>th</sup> edition, Olso, A. ed. (1980).

In another embodiment, the therapeutic agent of the present invention is  
30 provided in the form of cellular material. As contemplated in the present invention, cellular material means material that is obtained from differentiated cells with a different phenotype (such as smooth muscle cells, endothelial cells, and fibroblasts)

or with the same phenotype (such as myocardial cells). Alternatively, the cellular material is obtained from non-differentiated cells, such as mesenchymal cells.

Cellular material is introduced to the heart to repair, replace or enhance the biological function of damaged cells in order to strengthen a weakened heart.

- 5     Suspensions of cellular material can be injected into diseased cardiac tissue, and the implanted cells become important contributors towards normalization of structure and function of diseased tissue. In one preferred embodiment, cellular material is injected into the myocardium, which leads to incorporation of the cells into the tissue, cell contraction synchronous with adjacent cells, and an improvement in
- 10    cardiac hemodynamics. Cellular material includes myogenic cells, endocrine cells, islet cells, and any other suitable cell type desired for application using the invention described herein.

          The cells may be of a single tissue type or may contain a mixed population of cells. The cell culture may include cells that are xenogenic, allogenic and/or

15    isogenic to the host in which they are implanted. Propagation of vertebrate cells in culture is well known in the art (See, e.g., Tissue Culture, Academic Press, Kruse and Patterson, editors (1973)).

          The implanted cellular material may include culture media. Those of skill in the art are familiar with cell culture media. Examples of commercial available

20    media include Ham's F10 (Sigma), Minimal Essential Medium ("MEM", sigma), RPMI-1640 (Sigma), and Dulbecco's Modified Eagle's Medium ("DMEM", Sigma). The media may be supplemented as necessary with hormone and/or other growth factors, salts, buffers, nucleosides, antibiotics and trace elements (inorganic compounds usually present at final concentrations in the micromolar range).

25    Alternately, the delivery source may allow nutrients to diffuse into the cavity to support the live cell culture.

          In one embodiment, the implanted cells produce a therapeutic agent that has a beneficial effect on the host. In this embodiment, the therapeutic agent can comprise one or more of the therapeutic agents discussed *supra*.

30            In one embodiment of the invention, the implanted cells can be genetically engineered transformed cells. As used herein, the term "transformed cells" refers to cells in which an extrinsic DNA or gene construct has been introduced such that the



DNA is replicable, either as an extrachromosomal element or by chromosomal integration. Transformation of the cells is accomplished using standard techniques known to those of skill in the art and is described, for example, by Sambrook et al., Molecular Cloning: A Laboratory Manual, New York, Cold Spring Harbor

5 Laboratory Press (1989).

Extrinsic DNA or gene construct refers to a nucleic acid sequence originating outside a recipient cell and introduced into a recipient cell by a DNA delivery technique. A DNA or gene construct may be manufactured using recombinant DNA technology known in the art, or may be a nucleic acid fragment purified from a

10 source material. The extrinsic gene may be entirely composed of homologous sequence, i.e., sequences cloned, isolated, or derived from the same species from which the recipient cells derive. Alternatively, all or a portion of the extrinsic gene may be composed of sequences from species other than the species from which the recipient cells derive, hereinafter termed heterologous sequences. The extrinsic gene

15 construct may be natural in that none of the regulatory sequences and coding sequences that may be a part of the gene are substantially or intentionally altered, or the extrinsic gene construct may be chimeric in that sequence fragments from various sources are present in the final gene construct.

In one embodiment, cellular material is selected from smooth muscle cells,

20 endothelial cells, mesenchymal stem cells, and fibroblasts and is introduced into the cardiac environment using transdifferentiation. Transdifferentiation is a procedure such as that described by Kessler et al., that involves the conversion of a committed, differentiated, or specialized cell to another differentiated cell type with a distinctly different phenotype (See Myoblast Cell Grafting Into Heart Muscle: Cellular

25 Biology and Potential Applications, P.D. Kessler et al., *Annu. Rev. Physiol.* 1999, 61:219-42). In the present invention, smooth muscle cells, endothelial cells, mesenchymal stem cells, and/or fibroblasts from a donor can be provided in connection with the delivery source (e.g., the cells can be seeded onto the surface of the delivery source, as discussed in more detail below), to provide a source of

30 cellular material for transdifferentiation.

In another embodiment, the cellular material comprises myogenic cells that are grafted onto the surface of the heart. In this aspect, new myogenic cells, such as

cardiomyocytes, are introduced into the myocardium for repair of the heart. As used herein, grafting includes coating or impregnating cardiomyocytes onto or within the delivery source for application to the surface of the heart, or injecting cardiomyocytes into the heart muscle through direct epicardial injection. Preferably, myogenic cells are harvested from the patient receiving treatment, to minimize rejection of the cells.

In one embodiment, the jacket material serves as a scaffold onto which the matrix material containing the therapeutic agent is attached. For example, contractile cells can be seeded or sodded into/onto the jacket in such a way that the jacket material serves as a scaffold for support of the cells. As described herein, the cells can be harvested from a patient culture and applied to the jacket material. Alternatively, mesenchymal cells can be harvested from another patient and applied to the jacket material. In either event, these cells can then be adapted to perform contractile work, much in the way that skeletal muscle is adapted to the requirements for contraction in association with cardiomyoplasty. Cells implanted on/in the jacket can be exposed to an oriented electric field in such a way that the cells orient into a contractile element. Optimally, the biocompatible material comprising the material of the jacket is itself designed and oriented in the proper direction(s) of muscle contraction (i.e., in line with muscle fibers of the heart). The cells contained on the device are then capable of being stimulated using an electronic pacemaker, synchronous with the heart. Approaches to replacing myocardial scar tissue with cardiac cells are discussed, for example, by Li et al., in Cell Therapy to Repair Broken Hearts, Can. J. Cardiol. 14, 5: 735-744 (1998).

Myocardial cells, or other viable cell population can be attached to the jacket by various specific and non-specific means. Cells can be cultured directly onto the fabric of the jacket. Under suitable circumstances, cells can be promoted to completely cover the jacket surface. In the case of myocytes, the cells can be made to contract synchronously, perhaps providing a synthetic active contractile element to support the heart. Attachment of cells to the jacket can be via a spacer arm covalently attached to the jacket backbone polymer. This spacer arm, typically consisting of a string of methylene groups, or natural or synthetic peptides, is structured to have a biologically active attachment group at its terminus, which

would interact with a receptor on the cell surface. One example would be use of a poly-lysine peptide (or other such backbone) which terminates with an rgd (arginine-glycine-aspartic acid) sequence. The rgd sequence is known to bind with specific cell surface receptors, stabilizing attachment of cells. Similar examples have been  
5 used in construction of prosthetic vascular grafts, in which rgd peptides are incorporated into the graft to facilitate binding and stabilization of endothelial cells.

Cellular material introduced to the surface of the heart has a variety of clinical applications. For example, implanted cells can provide a platform for protein delivery at the surface of the heart. In this embodiment, cells provide a  
10 continual source of protein delivery at the surface of the heart to promote myocardial repair and to enhance growth of the transplanted cells. For example, myocytes can be altered genetically to deliver recombinant TGF- $\beta$ 1 or other effector to the heart. Additionally, neurotrophic factors and/or angiogenic factors, such as vascular endothelial growth factor or fibroblast growth factor, can be locally expressed to  
15 avoid the potentially harmful effects of systemic delivery of these proteins.

The delivery source of the invention can be provided in a variety of suitable forms. In one embodiment, the delivery source comprises a coating that is provided on, and/or impregnated into, the material of the jacket. Alternatively, the delivery source comprises a separable delivery source that is provided in association with the  
20 jacket.

In one embodiment, the delivery source is provided as a coating on, and/or impregnated into the material of, the jacket of the device. In this embodiment, the coating comprises a matrix material and one or more therapeutic agents. As used herein, the matrix material is a biologically and pharmacologically compatible  
25 and/or biodegradable material that can be adapted to include one or more therapeutic agents. Preferably, the matrix material is flexible and permeable to the therapeutic agent, to provide a suitable source for controlled release of the agent. Examples of suitable matrix materials include and polymeric matrix materials and hydrogels.

The coating can be applied to the jacket in any suitable fashion, using  
30 methods known in the art, e.g., by dipping, coating, spraying, or impregnating the coating onto the jacket. The porous, knit biocompatible jacket material, as described herein, is particularly well suited for application of the therapeutic agent by coating

or impregnation. The coating can be provided on the fibers 20 that form fiber strands 21a and 21b of the knit jacket material only, or the coating can be provided as a uniform coating of both the fibers 20 and the open cells 23 of the jacket. The viscosity of the coating will determine whether the coating is provided as a coating of the fibers only or as a uniform coating of the fibers and open cells. Viscosity of the coating is determined by such factors as the percent solids of the coating, and the molecular weight of the polymer.

The knit material of the jacket provides numerous advantages in connection with the delivery source. In one embodiment, the coating is provided on the individual fibers that form fiber strands 21a and 21b of the knit jacket. As described above, the individual fibers are interwoven along axes  $X_a$  and  $X_b$ . The interwoven fiber strands provide an increased surface area for coating, as compared to single fiber strands or strands that are provided in side-by-side arrangement. Also, coating along the fibers only maintains the open, interstitial spaces of the knit, which in turn provides advantages of the material mentioned above.

Alternatively, the coating is provided as a uniform coating that not only coats the fibers, but also fills the interstitial spaces of the jacket. In this embodiment, the overall surface area of the delivery source is further increased, as the coating is provided not only on the surfaces of the fibers of the jacket, but also fills the interstitial spaces defined by the fibers. The interstitial spaces serve as reservoirs for the coating, providing spaced-apart areas of concentrated coating containing the therapeutic agent. At the same time, the advantages of the jacket are maintained, such as the flexibility of the jacket and contact with the heart that is intimate and non-shifting.

Whether the coating is provided along the fiber strands only, or over both the fiber strands and open cells, the flexibility of the jacket is maintained. The directional expansion properties of the knit material allows the delivery source of the device to maintain intimate contact with the surface of the heart so that one or more therapeutic agents can be released directly to the surface of the heart and/or target tissue surrounding the heart. The coating itself is sufficiently flexible so that it does not fracture and fall or peel off from the material, but rather expands along with the jacket material. Further, because the jacket surrounds the heart and expands along

with the heart during its natural movement, the delivery source is maintained in intimate contact with the surface of the heart for prolonged periods of time. The device is not loosened by natural movement of the heart, and therefore delivery of one or more therapeutic agents that is intimate and non-shifting can be provided for  
5 prolonged periods of time.

The coating can be provided at any suitable location on the jacket, including a selected portion, or the entire surface area, of the jacket. For example, a portion of the jacket overlying an area of ischemia can be provided with suitable therapeutic agents in that selected area only, while anti-fibrotic agents can be provided on  
10 another selected area, or the entire area, of the jacket at the same time. The method of coating the jacket can be modified to achieve the desired coating area.

The coating on the jacket is provided in suitable thickness to provide an adequate dosage of the agent to achieve the desired effect, while controlling the release of the agent to the target tissue. Other factors influencing the thickness of  
15 the coating include the size of the therapeutic agent, release kinetics of the agent, and hydrophobicity or hydrophilicity of the agent versus the coating. At the same time, the coating is not provided in a thickness that would adversely affect the flexibility of the jacket material. For example, as the thickness of the coating increases, the mass that the heart is required to move during diastole increases. As a  
20 result, the thicker the coating, the less flexible the jacket becomes, and the greater the risk of fibrosis from the jacket. As presently contemplated, the final (total) thickness of the coating is generally in the range of approximately 0.5 mm to approximately 4 mm, preferably in the range of approximately 0.5 mm to approximately 2 mm, and optimally in the range of approximately 0.5 mm to  
25 approximately 1 mm. However, it is to be understood that the final thickness of the coating can be adjusted to any suitable thickness that provides the advantages and characteristics herein described. The coating can be formed by applying a single coating, or by applying multiple coatings to achieve a final desired thickness.

The matrix material of the coating is preferably a polymeric material or a  
30 hydrogel. Preferred polymeric materials are those that have a low degree of crystallization, and are biocompatible. In one embodiment, the polymeric matrix material is biodegradable. Examples of biodegradable polymers that can be used in

this embodiment include polylactides, polyglycolides, polycaprolactones, polyanhydrides, polyamides, polyurethanes, polyesteramides, polyorthoesters, polydioxanones, polyacetals, polyketals, polycarbonates, polyorthocarbonates, polyphosphazenes, polyhydroxybutyrates, polyhydroxyvalerates, polyalkylene oxalates, polyalkylene succinates, poly(malic acid), poly(amino acids), polyvinylpyrrolidone, polyethylene glycol, polyhydroxycellulose, chitin, chitosan, and copolymers, terpolymers, or combinations or mixtures of the above materials. The matrix material can also be provided in the form of a hydrogel. In this embodiment, the therapeutic agent(s) are released from the matrix by diffusion and/or degradation of the matrix material.

In an alternative embodiment, the polymeric matrix material is non-degradable, so that the matrix material remains part of the implanted device and is not broken down over time. Examples of suitable non-degradable materials include, for example, polyurethanes (such as polyether polyurethane), or silicone rubber materials (such as polydimethylsiloxane derivatives). In this embodiment, the therapeutic agent is released by diffusion of the agent through the matrix material.

Preferably, because both the degradable and non-degradable materials are intended to remain in the body for extended periods of time, these materials do not contain any leachable components that may be toxic to tissues.

Depending upon the desired softness and flexibility of the coating, and rate of release of the therapeutic agent, the amount and type of polymer can be varied to produce the desired result. For example, for a relatively soft and flexible polymer matrix, copolymers with a low T<sub>g</sub> can be used, primarily the lactide/caprolactone copolymers.

Preferably, the polymeric material is provided with a solvent that is non-toxic and biocompatible. Examples of suitable solvents include N-methyl-2-pyrrolidone, 2-pyrrolidone, ethanol, propylene glycol, acetone, methyl acetate, ethyl acetate, methyl ethyl ketone, dimethylformamide, dimethyl sulfoxide, dimethyl acetamide, tetrahydrofuran, caprolactam, decylmethylsulfoxide, oleic acid, and 1-dodecylazacycloheptan-2-one. One of skill in the art could readily determine the appropriate solvent for the polymeric matrix material, using such factors as

crystallinity, hydrophilicity, hydrogen-bonding and molecular weight of the polymeric material.

Typical application of a coating of the invention is as follows. The therapeutic agent(s) to be applied to the jacket are dissolved in a suitable solvent, such as dimethyl acetamide. In one embodiment, the therapeutic agent is soluble in the solvent, and a homogenous solution of the polymer and drug are applied to the jacket. Alternatively, the drug is not soluble in the solvent, and a suspension or dispersion of the drug in the solvent will result. The matrix material is also dissolved in the solvent. The therapeutic agent solution and matrix material solution are mixed, preferably forming a homogenous solution, although the solution may form a non-homogenous suspension. In either embodiment, the solvent will dissipate and the polymer solidifies and entraps or encases the therapeutic agent within the solid matrix.

The matrix material/therapeutic agent solution is then applied to the jacket, for example, by dip coating or other suitable method. The coated jacket is removed from the solution and optionally dried. The jacket is dried, for example, in a vacuum oven, or may be air dried, to evaporate the solvent from the jacket. The result is a thin film of the matrix material/therapeutic agent.

After placement of the device on the surface of the heart, the therapeutic agent is released from the coating into adjacent tissues by diffusion through the pores of the matrix material, and/or polymeric matrix degradation mechanisms. The rate and extent of release of the therapeutic agent from the delivery source are controlled over a range of speeds and amounts. Release of the therapeutic agent from the solid matrix will follow the same general rules for release of a therapeutic agent, such as a drug, from a monolithic polymeric device. Additionally, when the matrix material comprises a hydrogel polymer, the matrix material can be fabricated so that it swells in an aqueous environment, such as the body. In this embodiment, the hydrophilicity of the hydrogel can be altered (for example, by altering the polarity of the matrix material) to permit the desired water uptake. Such swelling of the matrix provides communication between the matrix and the adjacent tissues for delivery of a therapeutic agent.

Factors influencing the release rate include characteristics of the therapeutic agent, and characteristics of the overall coating. Characteristics of the therapeutic agent that influence release rate include water solubility, distribution within the matrix, concentration within the coating, chemical nature of attachment to the matrix material (i.e., chemical bond, if any), molecular weight, hydrophilicity or hydrophobicity, physical form, and the like. For example, release of a therapeutic agent having a low solubility in water, such as a lipid or other hydrophobic molecule, typically requires the degradation of a substantial part of the polymeric matrix to expose the material directly to the surrounding target tissue fluids.

The release rate is also influenced by characteristics of the overall coating that comprises a matrix material and therapeutic agent. For example, the polymeric matrix can be formulated to degrade after an effective and/or substantial amount of the therapeutic agent is released from the matrix. The release rate can be affected by the size and shape of the coating; material type and molecular weight of the matrix material; solubility, biodegradability, and/or hydrophilicity of the coating; permeability factors involving the therapeutic agent and the particular matrix material; degradation of the matrix; and the concentration and kinds of other additives present, if any, within the coating. Depending upon the therapeutic agent selected for use in the invention, the above parameters can be adjusted to give the desired rate and duration of release.

Generally, the thicker the coating, the greater the coating volume, and thus the amount of agent that can be incorporated into the coating. Consequently, a greater amount of a therapeutic agent can ostensibly be delivered from a thicker coating, and delivery can be tailored to occur over a greater time course. Other factors can influence delivery rate. Porosity in the coating, reflecting coating composition and density, can impact the ease of movement of therapeutic agents from the coating into adjacent cardiac tissue. Coating composition and chemical structure of the therapeutic agent or agents can influence the nature of interaction between these materials. If the therapeutic agent exhibits strong interaction with the coating, then the rate of release will be slow. For example, a polyurethane matrix coating containing hydrophilic moieties can be fashioned to provide a rapid release



vehicle for hydrophilic therapeutic agents. Likewise, a hydrophobic therapeutic agent will have slow release kinetics from a hydrophobic polymer coating.

Optionally, the matrix material is formulated to provide an initial burst effect. This results in a bolus dose of the therapeutic agent, followed by a relatively  
5 constant release of the agent over time. Factors contributing to a greater initial burst include the thickness of the coating, the particle size of the therapeutic agent, and amount of therapeutic agent included in the coating. For example, factors contributing to a greater initial burst include greater thickness of the coating, larger particle size of the therapeutic agent, and higher amount or concentration of the  
10 therapeutic agent.

The present invention provides a device that is capable of delivering a range of doses of therapeutic agent over prolonged periods of time. The amount of therapeutic agent incorporated into the coating is determined by the patient's physician. This amount depends upon such factors as the desired release profile,  
15 concentration of the drug required for a therapeutic effect, and length of time that the therapeutic agent has to be released for effective treatment. For example, a coating containing a higher weight percent of therapeutic agent will generally release a higher total amount of therapeutic agent to the target tissue. According to the invention, the coating contains approximately 1% (by weight) to approximately 40%  
20 (by weight) of the therapeutic agent. Preferably, the coating contains approximately 5% (by weight) to approximately 30% (by weight) of the of the therapeutic agent, more preferably, approximately 10% (by weight) to approximately 15% (by weight).

In one embodiment, as the polymeric matrix degrades, the therapeutic agent is released from the delivery source. The delivery source will release the therapeutic  
25 agent within the matrix at a controlled rate until the therapeutic agent is depleted. With certain therapeutic agents, the polymer will degrade after the agent has been completely released. With other therapeutic agents such as peptides or proteins, the agent will be completely released only after the polymer has degraded to a point where the non-diffusing drug has been exposed to the body fluids.

30

In one embodiment, the matrix material of the coating is provided in the form of a hydrogel polymer. In this embodiment, the hydrated polymer matrix allows

controlled release of the therapeutic agent to the target tissue. As discussed *supra*, the thickness of the hydrogel is controlled to vary the rate of release of the therapeutic agent. In contrast, when rapid release of the agent is desired, the thickness of the hydrogel is decreased. The ratio of therapeutic agent to hydrogel polymer in the matrix is adjusted to provide the desired release rate and dosage over  
5 time. Preferably, the hydrogel comprises at least 80% (v/v) water.

The hydrogel polymer is selected from polycarboxylic acids, water-swollen cellulose derivatives, gelatin, polyvinylpyrrolidone, maleic anhydride polymers, polyamides, poly(vinyl alcohol), polyethylene oxides, poly(2-hydroxyethyl  
10 methacrylate), poly(ethylene oxide), and copolymers thereof.

In one embodiment, the hydrogel polymer is characterized by the ability to incorporate a substantial amount of the therapeutic agent, typically in aqueous form, and is swellable such that the aqueous therapeutic agent solution can be effectively squeezed out of the coating when pressure is applied by natural expansion of the  
15 heart during diastole. The therapeutic agent is thus applied to the tissue in a gentle manner that avoids disrupting or injuring healthy cardiac or other tissue, while diffusion of the therapeutic agent into the tissue is facilitated by the application of the pressure exerted during diastole. At the same time, pressure between the heart and the jacket effectively forms a seal that prevents the therapeutic agent from  
20 diffusing to areas in the body other than the treatment area. The hydrogel polymer can be biodegradable or non-degradable, as described above for the polymeric matrix material.

Alternatively, the delivery source comprises a chemical/polymer bioadhesive system used to adhere the device of the invention to the heart. The polymer system  
25 used for adhesion of the jacket to the heart is modified to include one or more therapeutic agent(s). The amount of therapeutic agent included in the bioadhesive system is influenced by such factors as listed above, including desired dosage of the agent, solubility of the agent, and the molecular weight of the agent versus the molecular weight of the polymer. Moreover, how the agent loading affects the  
30 physical and/or chemical characteristics of the polymer bioadhesive will be considered.

In another embodiment of the present invention, the delivery source is provided as an element that is separate from the jacket of the device. The delivery source can be provided in the form of a patch containing the therapeutic agent of interest, or a bladder containing the therapeutic agent. Suitable patches and bladders are known in the art. For example, see Epicardial Administration of Ibutilide from Polyurethane matrixes: Effects on Defibrillation Threshold and Electrophysiologic Parameters, Labhasetwar et al., J. Of Cardiovascular Pharm., 24:826-840 (1994), Sotalol Controlled-Release Systems for Arrhythmias: In Vitro Characterization, In Vivo Drug Disposition, and Electrophysiologic Effects, Labhasetwar et al., J. of Pharm. Sciences, 83: 156-164 (1994).

When the delivery source comprises a bladder, the bladder is preferably refillable. Refilling the bladder can be achieved in any suitable manner, e.g., using a catheter connected to the bladder containing a proximal terminal connection just under the surface of the skin, or through a one-use direct injection of therapeutic agent from a disposable hypodermic needle.

In this embodiment, the jacket provides an anchoring surface for the delivery source that presses the delivery source against the surface of the heart and maintains the delivery source in position on the heart. According to the invention, the patch or bladder can be provided underneath the jacket 10, such that the delivery source is positioned between the jacket and the heart. The jacket presses the delivery source against the heart, without causing damage to the heart that would result from directly attaching the source at the treatment site, by sutures, adhesives or the like. The delivery source can be attached to the jacket, for example, using sutures or bioadhesives, to maintain the position of the delivery source in relation to the jacket. Alternatively, the patch or bladder can be held in place simply by the pressure of the jacket against the heart. Because the jacket itself is maintained in non-shifting contact with the heart, the delivery source is also provided with a non-shifting position on the surface of the heart. For example, the use of the jacket to maintain the positioning of the delivery source avoids such undesirable effects as fibrosis, necrosis, and the like.

The patch or bladder is fabricated from a biocompatible material, to avoid adverse effects associated with rejection, infection, and the like. The amount of

therapeutic agent provided in such patches or bladders depends upon such factors as those listed above for the delivery source as a coating.

Delivery of the therapeutic agent to target tissues can be achieved through passive as well as active delivery methods. Passive methods include diffusion of the agent from the delivery source, as discussed above. Active delivery mechanisms use an energy source to deliver the therapeutic agent to the target tissue.

Active delivery systems include systems that use an energy source to deliver one or more therapeutic agents to the target tissue. Suitable energy sources include external sources such pumps or sources of electrical current. For example, an osmotic pump can be used in connection with a bladder delivery source, to provide active delivery of agents from the bladder to target tissues. Examples of sources of electrical current include batteries and electrodes. For example, the device of the invention can utilize iontophoresis to deliver one or more therapeutic agents to the heart. Iontophoresis uses electrical current, through a direct myocardial electrode patch, to transport charged molecules into tissue. Iontophoretic methods are known in the art, as are methods using phonophoresis and battery-driven devices. Other suitable external energy sources include ultrasound, thermal energy, radiofrequency, or microwave energy.

In yet another embodiment, the natural movement of the heart is used as an energy source for therapeutic agent delivery. As described above, when the delivery source of the invention comprises a hydrogel, diastolic filling of the heart can drive release of the therapeutic agent from the hydrogel coating. In this embodiment, the hydrogel can be selected to allow release of a desired dosage of the therapeutic agent from the hydrogel polymer coating during compression of the hydrogel polymer coating against the heart or other tissue. The pumping action of the heart induces the device to release the agent, and the therapeutic agent is effectively released upon compression of the polymer coating on the device. When the heart expands during diastole, it exerts pressure against the jacket of the device, which in turn compresses the coating against the heart. Compression of the coating triggers release of the agent for transfer into or onto the target tissue. The pressure applied to the fluid therapeutic agent against the tissue by the jacket enhances transfer of the therapeutic agent into the tissue. The pressure is sufficient to allow release of the therapeutic

agent without damaging the tissue. Similarly, movement of the heart can be used to drive release of the therapeutic agent from a bladder or patch.

In another embodiment, one or more therapeutic agents are delivered to the surface of the heart by injecting the agents into the myocardium through  
5 microneedles provided on the surface of the delivery source. Preferably, the delivery source comprises a bladder, and fine microneedles are connected to the bladder to provide a channel through which the therapeutic agents are transported into myocardium. In one embodiment, pneumatic pressure for infusing the therapeutic agent is provided by pressurizing the bladder with a catheter containing a proximal  
10 terminal connection routed to a location just under the patient's skin for easy access. Alternatively, energy transduced from diastolic filling of the heart can provide pressure for infusing the therapeutic agent. Diastolic filling of the heart applies pressure to the bladder, as the expanding heart encounters the restraining force of the jacket. This in turn causes release of the agent to target tissues.

15 As contemplated by the present invention, a therapeutic agent can be delivered to the heart or surrounding tissue of interest for a period of from several minutes, to several weeks.

The present invention provides improved capacity to deliver one or more therapeutic agents to one or more selected sites on the heart surface. The jacket of  
20 the invention encompasses all or a part of the heart, and all, or one or more selected areas of the jacket can be provided with a delivery source according to the invention.

In a particular aspect, the invention provides a delivery source that can be either bi-directional or uni-directional. Bi-directional release of the therapeutic agent is desirable, for example, when preventing adhesion between the heart and  
25 surrounding tissues. For example, when the target tissue is the heart, the delivery source can be adapted to release the therapeutic agent towards the heart only. In one embodiment, this uni-directional release can be accomplished by providing a coating containing the therapeutic agent on the jacket facing the heart only. Alternatively, when the target tissue is the tissue surrounding the heart, the delivery device can be  
30 adapted to release the therapeutic agent away from the heart, and thus towards the target tissues.

In one embodiment, the jacket material of the device can be fashioned in such a way that therapeutic agents retained in the delivery source are released only in the direction of the heart by modifying the porosity of the jacket material. In this embodiment, the portion of the jacket facing or adjacent the heart has porosity large enough to allow the therapeutic agent to diffuse from the jacket and into the myocardium. The portion of the jacket facing away from the heart can be modified to be non-porous, or to contain pores of insufficient size to allow therapeutic agents to pass through. Alternatively, if the target tissue comprises tissue surrounding the heart, the jacket material can be modified such that therapeutic agent delivery is directed away from the heart, and towards the surrounding tissues. In yet another embodiment, an impermeable layer can be provided to create a barrier to prevent delivery of the therapeutic agent to a particular area of tissue. Delivery of the agent will, in this embodiment, occur in a direction opposite the barrier.

When the delivery source is provided in the form of a separate bladder or patch, the permeability of the delivery source can be adapted to allow selective release of the agent to target tissues, using the modification of porosity described above for the coating. Alternatively, an impermeable layer, as discussed above, can be provided in connection with the bladder or patch, to achieve directed delivery of the agent.

In one embodiment, the present invention provides for delivery to selected target areas of the heart and/or surrounding tissue. In this embodiment, delivery of the therapeutic agent is precisely controlled, so that only selected areas are exposed to the agent. This can be achieved, for example, by coating only a desired area of the jacket with the therapeutic agent, when the delivery source is provided in the form of a coating on the jacket. Alternatively, when the delivery source comprises a separate bladder or patch, the location of the delivery source can be controlled to expose only a limited target area to the agent or agents. For example, it may be desirable to apply an anti-fibrotic agent over areas of the heart including arteries, so that if it is necessary to access the arteries for future coronary artery repair, there would be no adhesion between the jacket and the heart.

Unlike solid drug delivery devices known in the art, the present invention provides a jacket of a knit biocompatible material that provides sustained, controlled

release of a therapeutic agent to the heart or other target tissue. When the delivery source comprises a coating on the jacket, the jacket material provides a larger surface area for application of therapeutic agent(s), as well as a flexible device to maintain intimate, non-shifting contact with the target tissue. The structure of the knit material allows the device to carry larger dosages of one or more therapeutic agents. Moreover, the jacket of the invention can be adapted to encompass the lower portion of the heart, the upper portion of the heart, or substantially the entire surface of the heart. Regardless of the surface area of the heart encompassed by the jacket of the invention, the delivery source of the device can be located at any desired target area, e.g., a specific surface artery of the heart or area of ischemia or necrosis.

It is understood that although the invention has been described in connection with heart applications, the methods and device described herein can be readily adapted for a variety of tissues in the body, using the teachings herein.

While a preferred embodiment of the present invention has been described, it should be understood that various changes, adaptations and modifications may be made therein without departing from the spirit of the invention and the scope of the appended claims.

What is claimed is:

1. A device for treating cardiac disease of a heart having an upper portion and a lower portion divided by an A-V groove, the device comprising:
  - 5 a. a jacket of flexible material defining a volume between an upper end and a lower end, the jacket adapted to be secured to the heart and adapted to be adjusted on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain circumferential expansion of the heart beyond the maximum adjusted volume during diastole and permit substantially unimpeded contraction of the heart during systole; and
  - 10 b. a delivery source for the delivery of one or more therapeutic agents to the surface of the heart.
- 15 2. The device according to claim 1 wherein the jacket comprises an elastic material.
3. The device according to claim 1 wherein the flexible material is sufficiently flexible to gather excess amounts of the material following placement of the jacket over the heart to snugly conform the material to an external geometry of the heart.
- 20 4. The device according to claim 1 wherein the flexible material is selected from polytetrafluoroethylene, expanded polytetrafluoroethylene, polypropylene, polyester and stainless steel.
- 25 5. The device according to claim 1 wherein the jacket surrounds the lower portion of the heart.
6. The device according to claim 1 wherein the jacket surrounds the upper portion of the heart.
- 30 7. The device according to claim 1 wherein the device provides localized delivery of one or more therapeutic agents to a target area on the surface of the heart.



8. The device according to claim 1 wherein the device provides bi-directional delivery of one or more therapeutic agents to the surface of the heart and an area surrounding the heart.

5

9. The device according to claim 1 wherein the one or more therapeutic agents comprise one or more pharmacological agents.

10. The device according to claim 1 wherein the one or more therapeutic agents  
10 comprise cellular material.

11. The device according to claim 10 wherein the cellular material comprises myocytes.

15 12. The device according to claim 1 wherein the delivery source comprises a coating on the jacket.

13. The device according to claim 12 wherein the coating comprises a matrix material and the therapeutic agent.

20

14. The device according to claim 13 wherein the matrix material is biodegradable.

15. The device according to claim 1 wherein the delivery source comprises a separable element from the jacket.

25

16. The device according to claim 15 wherein the separable element is a bladder or a patch.

17. The device according to claim 15 wherein the separable element is a  
30 bioadhesive.

18. The device according to claim 1 wherein the jacket actively assists in delivery of the therapeutic agent to the surface of the heart.

19. A method for treating cardiac disease of a heart having an upper portion and a lower portion divided by an A-V groove, the method comprising:
- a. surgically accessing the heart;
  - b. applying a treatment device on the heart, the device comprising:
    - 1) a jacket of flexible material defining a volume between an upper end and a lower end, the jacket adapted to be secured to the heart and adapted to be adjusted on the heart to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain circumferential expansion of the heart beyond the maximum adjusted volume during diastole and permit substantially unimpeded contraction of the heart during systole; and
    - 2) a delivery source for the delivery of one or more therapeutic agents to the surface of the heart;
  - c. securing the treatment device to the heart; and
  - d. surgically closing access to the heart while leaving the treatment device on the heart.

20. The method according to claim 19 wherein the jacket actively assists in delivery of the one or more therapeutic agents to the surface of the heart.

21. A method for providing controlled and sustained administration of one or more therapeutic agents effective in treating cardiac disease, the method comprising surgically implanting a sustained therapeutic agent delivery system at a desired location on the heart, the therapeutic agent delivery system comprising:

- a. a jacket of flexible material defining a volume between an upper end and a lower end, the jacket adapted to be secured to the heart and adapted to be adjusted on the heart to snugly conform to an external geometry of the heart

and assume a maximum adjusted volume for the jacket to constrain circumferential expansion of the heart beyond the maximum adjusted volume during diastole and permit substantially unimpeded contraction of the heart during systole; and

- 5        b. a delivery source for the delivery of one or more therapeutic agents to the surface of the heart.

22. The method according to claim 21 wherein the jacket actively assists in delivery of the therapeutic agent to the surface of the heart.

10

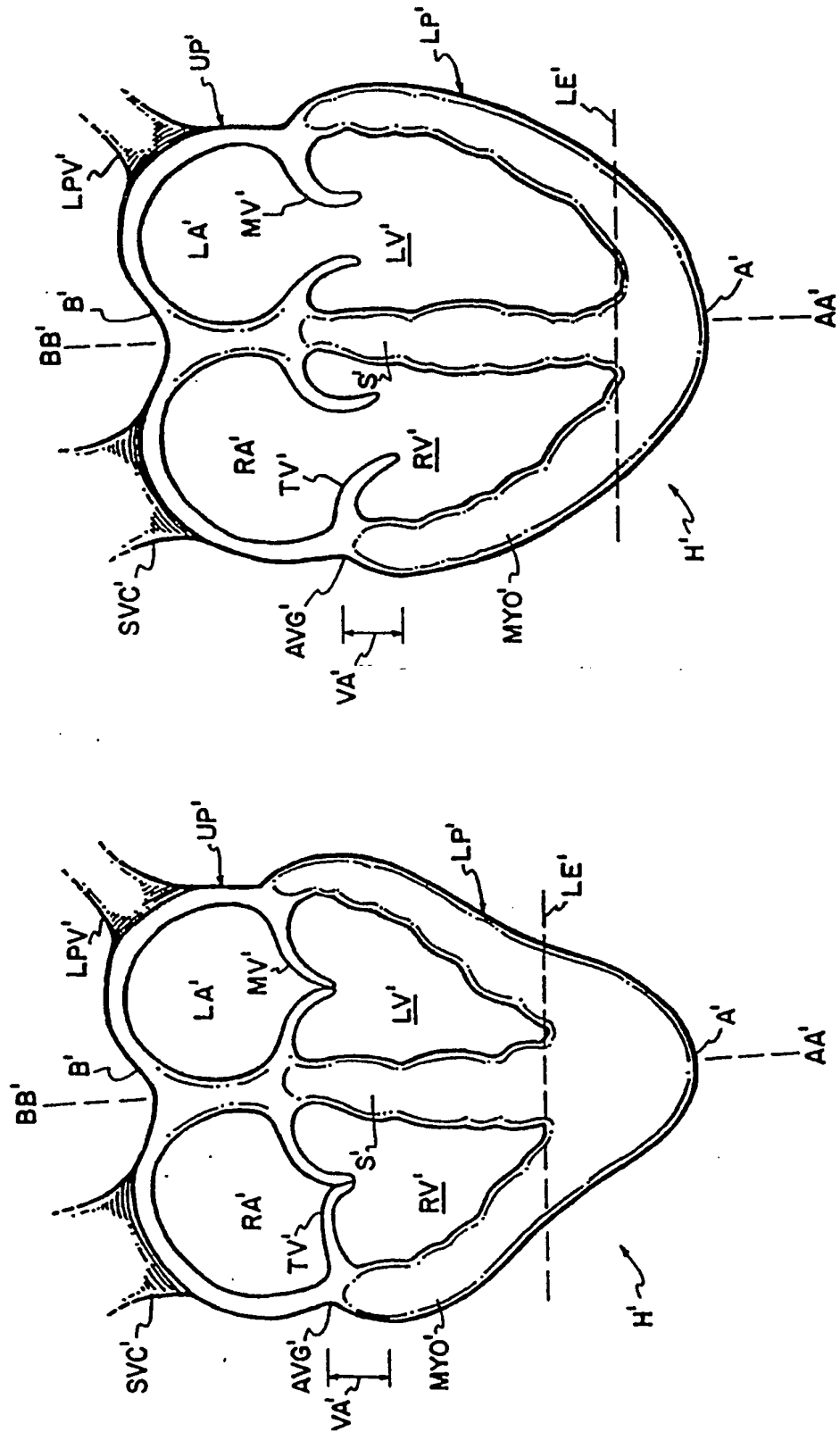


FIG. 1A

FIG. I

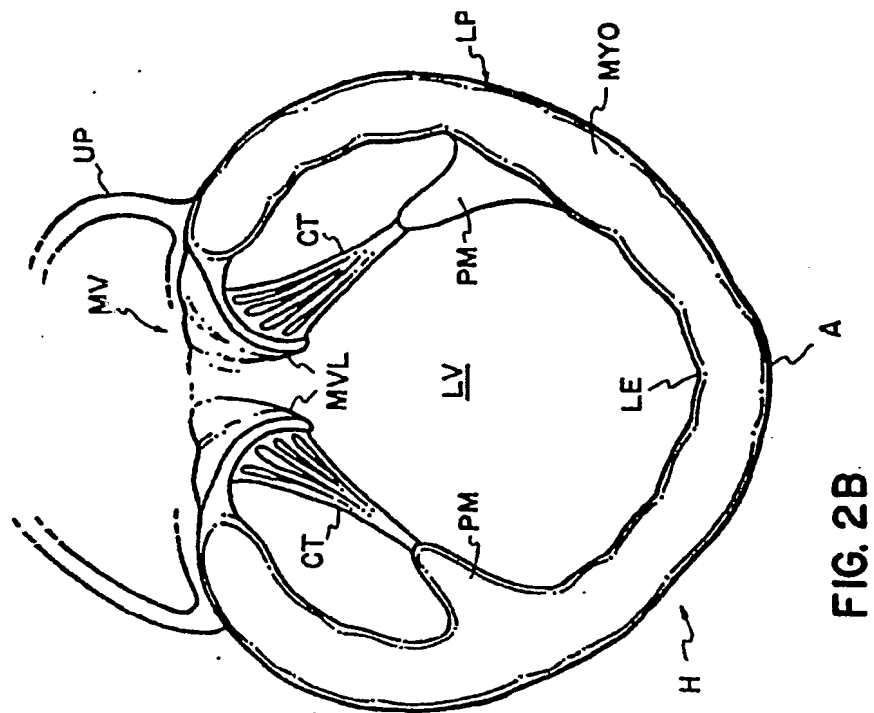


FIG. 2B

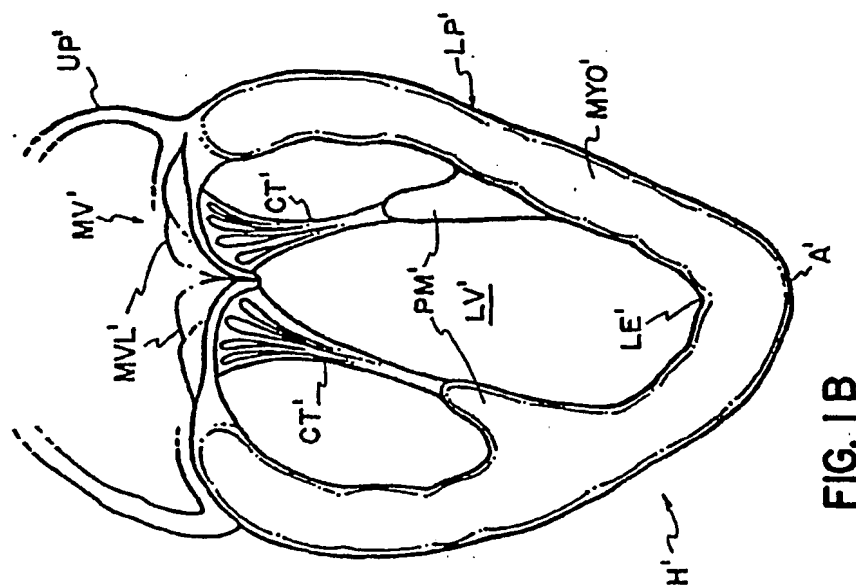
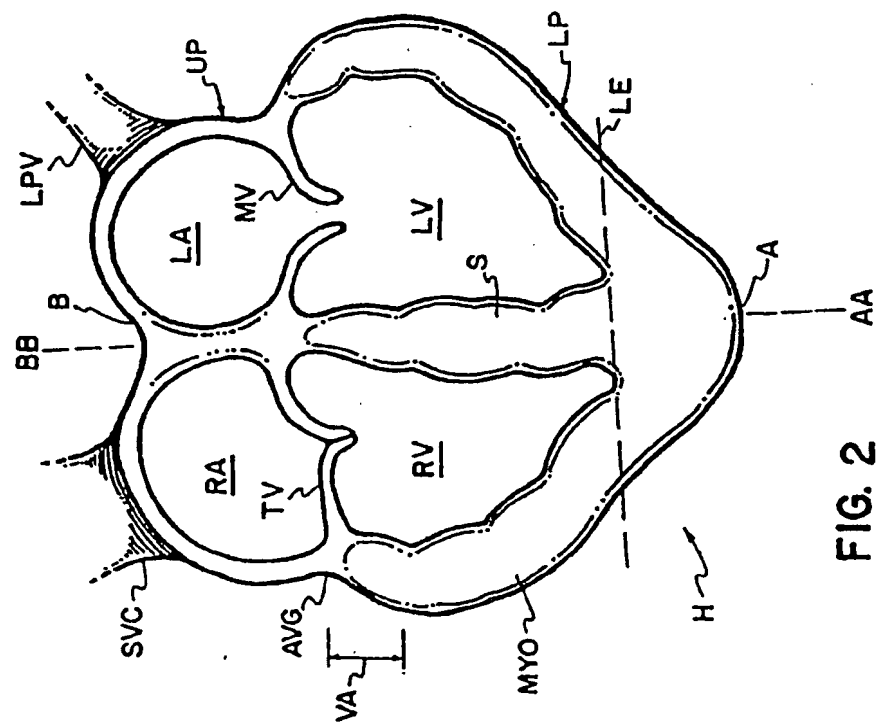
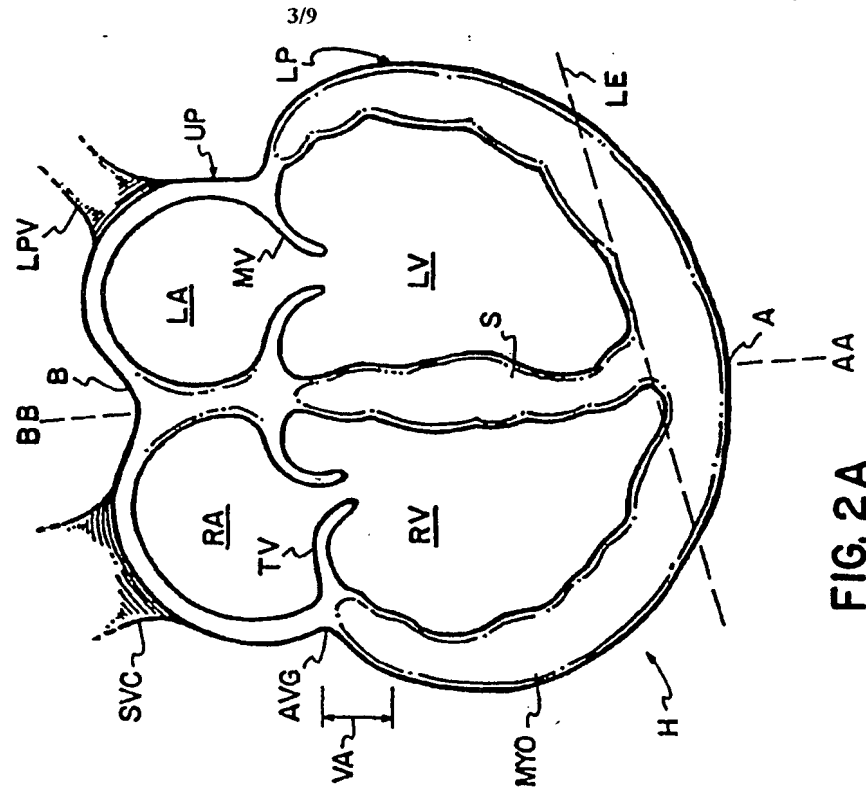


FIG. 1B



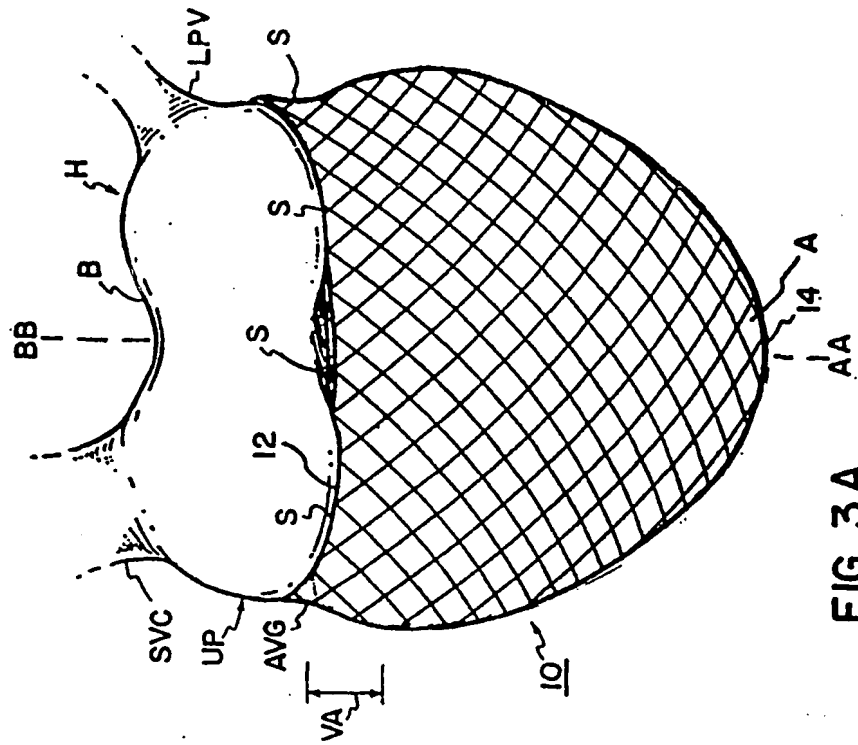


FIG. 3A

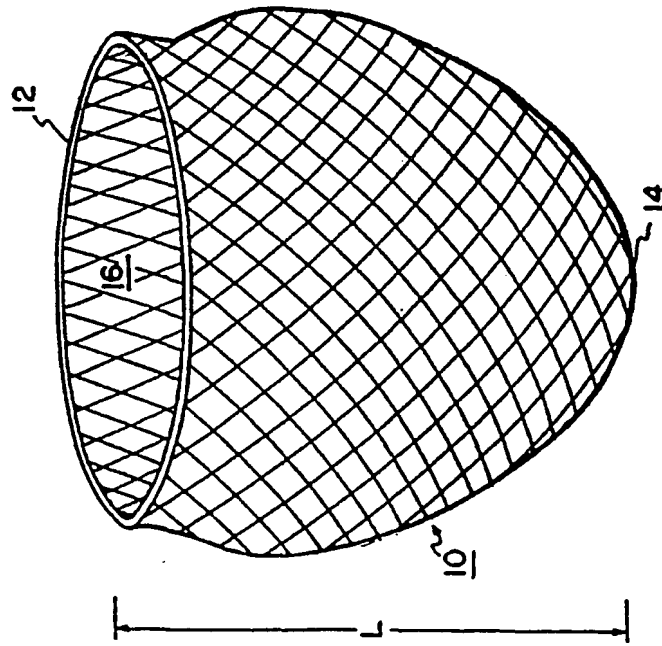


FIG. 3

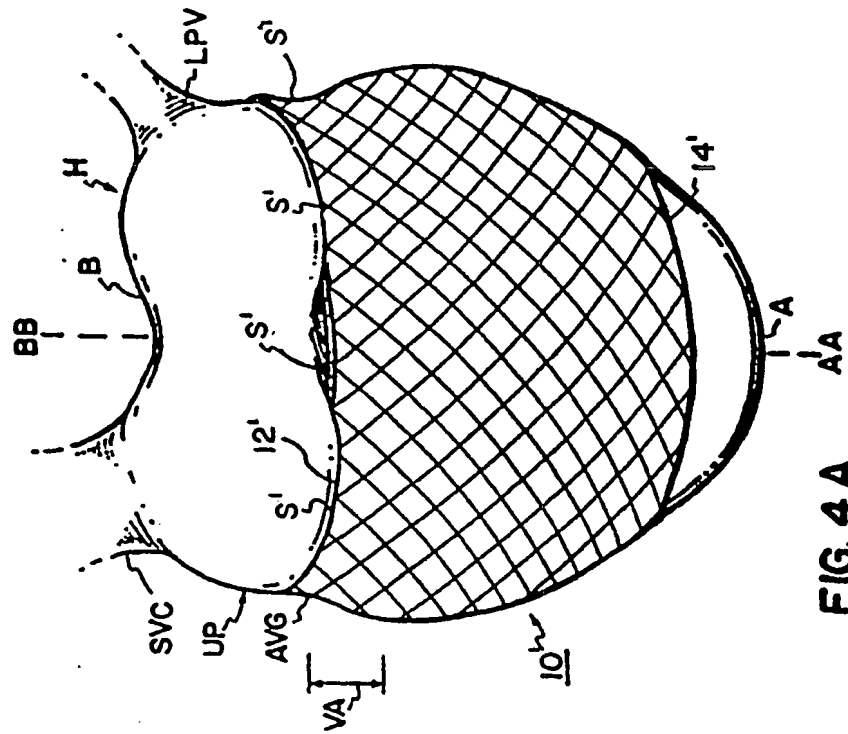


FIG. 4 A

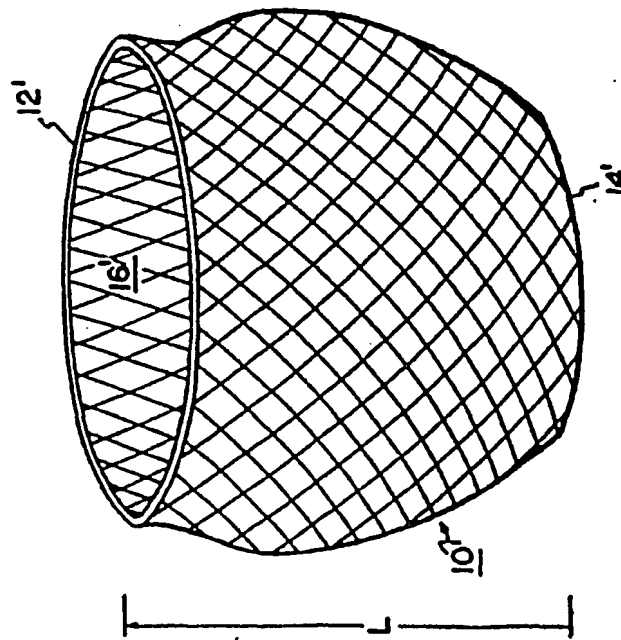


FIG. 4



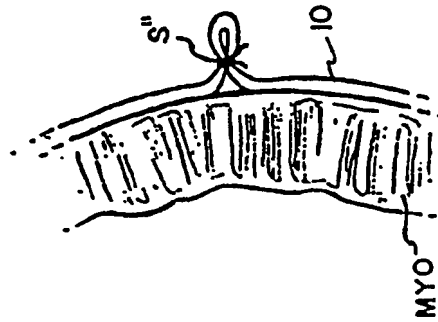


FIG. 5

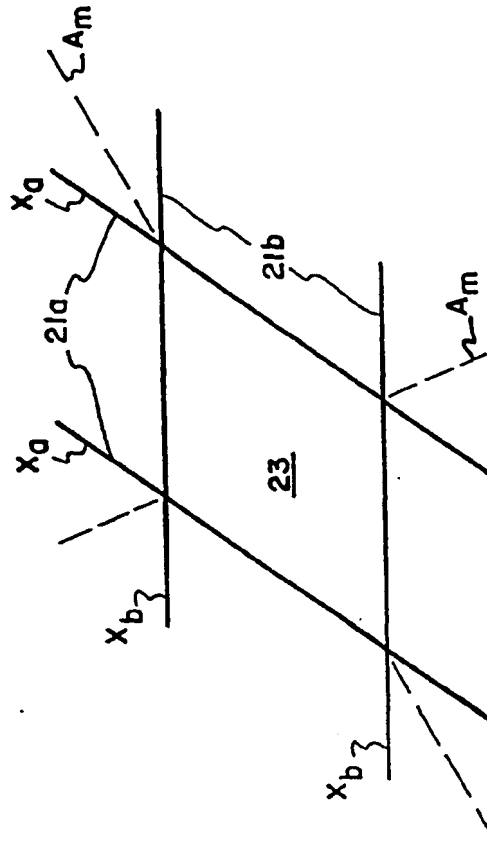
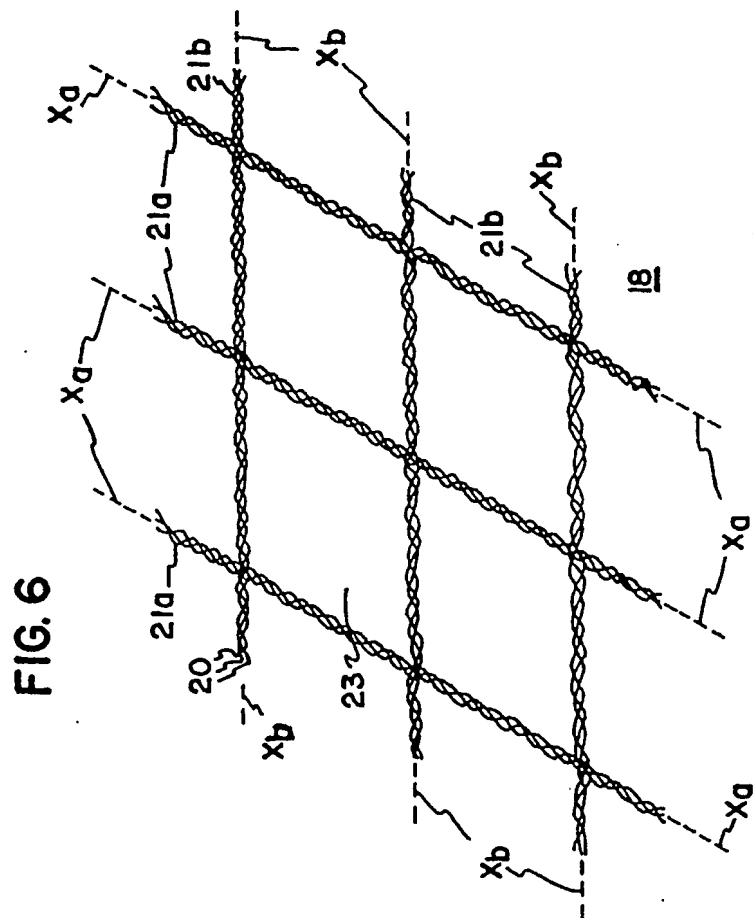


FIG. 7



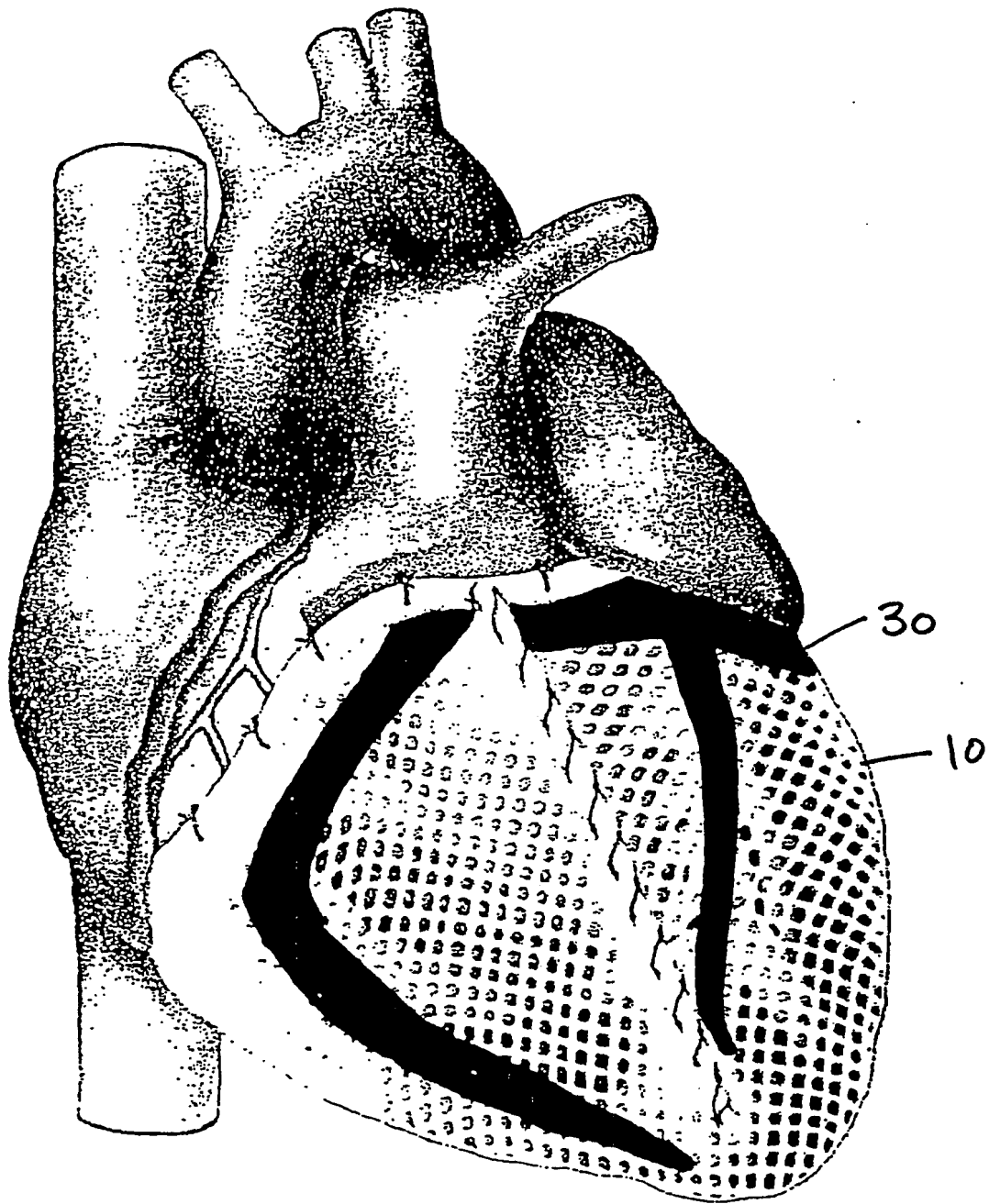


FIG. 8

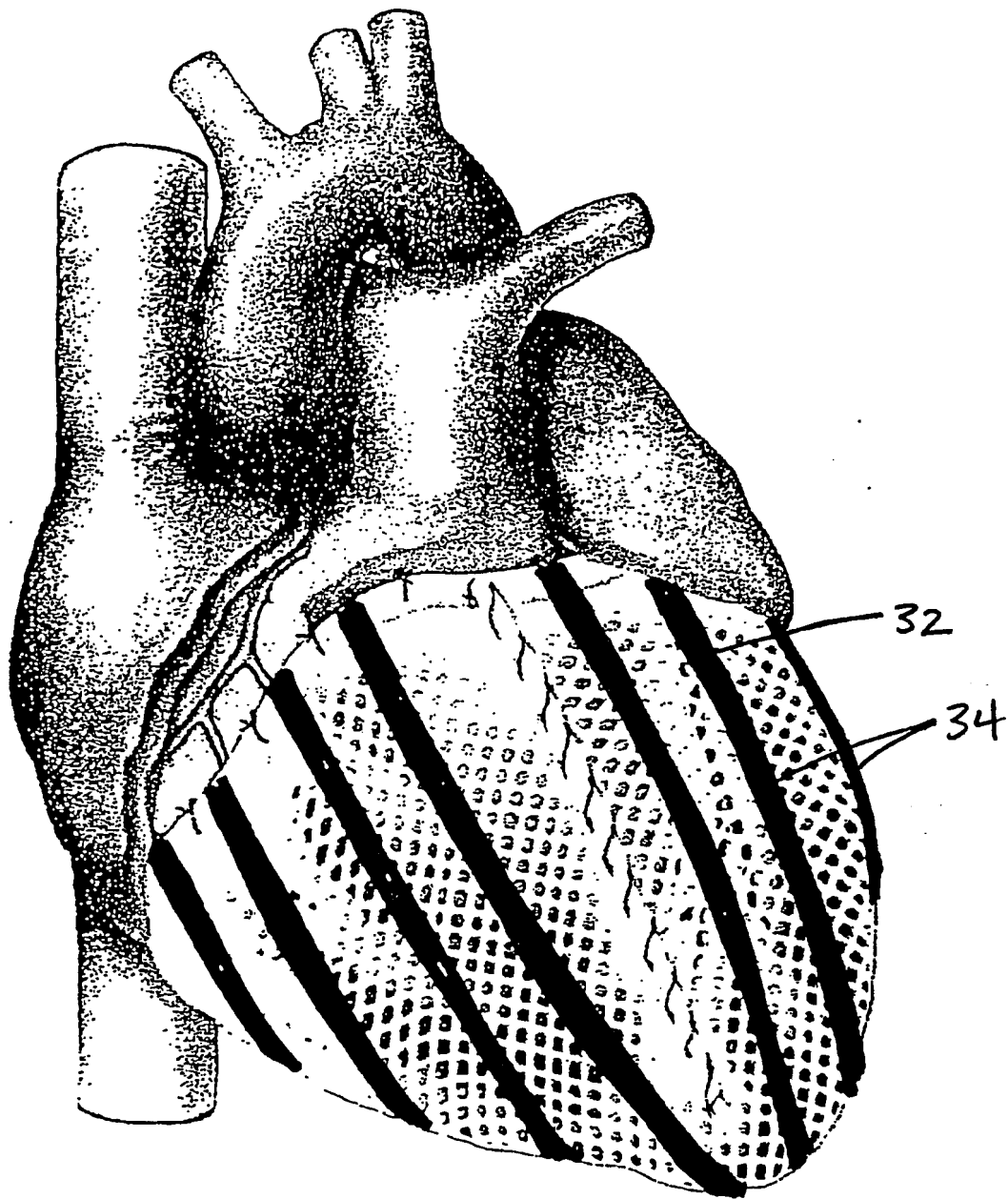


FIG. 9.

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(54) Title: CARDIAC DISEASE TREATMENT AND DEVICE

(57) Abstract: A method and device are disclosed for treating congestive heart disease. The material of the device is secured to the heart proximate the septal wall. The material covering the ventricles may or may not have the same tension and/or compliance. The device can be constructed as a unitary "jacket" that is slipped over the apex of the heart. Alternately, the device implanted as one, two or more separate components. In one embodiment, the material covers only one ventricle. The device may include at least one adjustment mechanism configured to adjust the tension of the material. Preferably, the device includes a first adjustment mechanism configured to adjust a tension of the material covering the right ventricle and a second adjustment mechanism configured to adjust the tension of the material covering the left ventricle such that the tension of the material covering the left ventricle can be different than the tension of the material covering the right ventricle.

## CARDIAC DISEASE TREATMENT AND DEVICE

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

5           The present invention is directed to a method and device for treating congestive heart disease and related valvular dysfunction. More particularly, the invention provides a cardiac support device with sections having variable compliance.

#### 10   2. Description of the Prior Art

          Congestive heart disease is a progressive and debilitating illness. The disease is characterized by a progressive enlargement of the heart.

          As the heart enlarges, the heart is performing an increasing amount of work  
15   in order to pump blood each heart beat. In time, the heart becomes so enlarged the heart cannot adequately supply blood. An afflicted patient is fatigued, unable to perform even simple exerting tasks and experiences pain and discomfort. Further, as the heart enlarges, the internal heart valves cannot adequately close. This impairs the function of the valves and further reduces the heart's ability to supply blood.

20           Causes of congestive heart disease are not fully known. In certain instances, congestive heart disease may result from viral infections. In such cases, the heart may enlarge to such an extent that the adverse consequences of heart enlargement continue after the viral infection has passed and the disease continues its progressively debilitating course.

25           Patients suffering from congestive heart disease are commonly grouped into four classes (i.e., Classes I, II, III and IV). In the early stages (e.g., Classes I and II), drug therapy is the commonly prescribed treatment. Drug therapy treats the symptoms of the disease and may slow the progression of the disease. Importantly, there is no cure for congestive heart disease. Even with drug therapy, the disease  
30   will progress. Further, the drugs may have adverse side effects.

          Presently, the only permanent treatment for congestive heart disease is heart transplant. Heart transplant procedures are very risky, extremely invasive and

expensive and only shortly extend a patient's life. Furthermore, not enough hearts are available for transplant to meet the needs of congestive heart disease patients and many patient's do not qualify for heart transplant for failure to meet any one of a number of qualifying criteria.

5           Substantial effort has been made to find alternative treatments for congestive heart disease. Recently, a new surgical procedure has been developed. Referred to as the Batista procedure, the surgical technique includes dissecting and removing portions of the heart in order to reduce heart volume. This is a radical new and experimental procedure subject to substantial controversy. Furthermore, the  
10           procedure is highly invasive, risky and expensive and commonly includes other expensive procedures (such as a concurrent heart valve replacement). Also, the treatment is limited to Class IV patients and, accordingly, provides no hope to patients facing ineffective drug treatment prior to Class IV. Finally, if the procedure fails, emergency heart transplant is the only available option.

15           Clearly, there is a need for alternative treatments applicable to both early and later stages of the disease to either stop the progressive nature of the disease or more drastically slow the progressive nature of congestive heart disease. Unfortunately, currently developed options are experimental, costly and problematic.

            Cardiomyoplasty is a recently developed treatment for earlier stage  
20           congestive heart disease (e.g., as early as Class III dilated cardiomyopathy). In this procedure, the latissimus dorsi muscle (taken from the patient's shoulder) is wrapped around the heart and chronically paced synchronously with ventricular systole. Pacing of the muscle results in muscle contraction to assist the contraction of the heart during systole.

25           While cardiomyoplasty has resulted in symptomatic improvement, the nature of the improvement is not understood. For example, one study has suggested the benefits of cardiomyoplasty are derived less from active systolic assist than from remodeling, perhaps because of an external elastic support. The study suggests an elastic support (i.e., a non-stimulated muscle wrap or an artificial elastic sock placed  
30           around the heart) could provide similar benefits. Kass et al., *Reverse Remodeling From Cardiomyoplasty In Human Heart Failure: External Support Versus Active Assist*, 91 Circulation 2314 – 2318 (1995).

Even though cardiomyoplasty has demonstrated symptomatic improvement, studies suggest the procedure only minimally improves cardiac performance. The procedure is highly invasive requiring harvesting a patient's muscle and an open chest approach (i.e., sternotomy) to access the heart. Furthermore, the procedure is  
5 expensive -- especially those using a paced muscle. Such procedures require costly pacemakers. The cardiomyoplasty procedure is complicated. For example, it is difficult to adequately wrap the muscle around the heart with a satisfactory fit. Also, if adequate blood flow is not maintained to the wrapped muscle, the muscle may necrose. The muscle may stretch after wrapping reducing its constraining benefits  
10 and is generally not susceptible to post-operative adjustment. Finally, the muscle may fibrose and adhere to the heart causing undesirable support on the contraction of the heart during systole.

In addition to cardiomyoplasty, mechanical assist devices have been developed as intermediate procedures for treating congestive heart disease. Such  
15 devices include left ventricular assist devices ("LVAD") and total artificial hearts ("TAH"). An LVAD includes a mechanical pump for urging blood flow from the left ventricle and into the aorta. An example of such is shown in U.S. Patent No. 4,995,857 to Arnold dated February 26, 1991. LVAD surgeries are still in U.S. clinical trials and not generally available. Such surgeries are expensive. The  
20 devices are at risk of mechanical failure and frequently require external power supplies. TAH devices, such as the celebrated Jarvik heart, are used as temporary measures while a patient awaits a donor heart for transplant.

Other attempts at cardiac assist devices are found in U.S. Patent No. 4,957,477 to Lundbäck dated September 18, 1990, U.S. Patent No. 5,131,905 to  
25 Grooters dated July 21, 1992 and U.S. Patent No. 5,256,132 to Snyders dated October 26, 1993. Both of the Grooters and Snyders patents teach cardiac assist devices which pump fluid into chambers opposing the heart to assist systolic contractions of the heart. The Lundbäck patent teaches a double-walled jacket surrounding the heart. A fluid fills a chamber between the walls of the jacket. The  
30 inner wall is positioned against the heart and is pliable to move with the heart. Movement of the heart during beating displaces fluid within the jacket chamber.



Commonly assigned U.S. Patent No. 5,702,343 to Alferness dated December 30, 1997 teaches a jacket to constrain cardiac expansion during diastole. The present invention pertains to improvements to the invention disclosed in the '343 patent.

5

### SUMMARY OF THE INVENTION

According to a preferred embodiment of the present invention, a method and device are disclosed for treating congestive heart disease and related cardiac complications such as valvular disorders. The invention includes a device constructed from biologically compatible material dimensioned to cover at least one  
10 ventricle of the heart. The device is adapted to be secured to the heart and is adjustable to snugly conform to an external geometry of the heart and assume a maximum adjusted volume for the jacket to constrain circumferential expansion of the heart beyond the maximum adjusted volume during diastole and to permit unimpeded contraction of the heart during systole.

15 In particular, the invention provides a device constructed such that material covering one ventricle can have a different a compliance or tension than material covering the other ventricle. In a preferred embodiment, the material of the device is secured to the heart proximate the septal wall.

The device can be constructed as a unitary "jacket" that is slipped over the  
20 apex of the heart (See, for example, U.S. Patent No. 5,702,343 to Alferness, dated December 30, 1997, the disclosure of which is incorporated by reference herein). Alternately, the device may be implanted as two or more separate components (pieces of material). In one embodiment, the device covers both the left and right ventricles. In another embodiment, the device covers only the left ventricle or only  
25 the right ventricle.

Preferably, the device includes at least one adjustment mechanism configured to adjust the tension of the material. More preferably, the device includes a first adjustment mechanism configured to adjust a tension of the material covering the right ventricle and a second adjustment mechanism configured to adjust  
30 the tension of the material covering the left ventricle such that the tension of the material covering the left ventricle can be different than the tension of the material covering the right ventricle.

The invention also provides a method for implanting the device, both as a unitary device, or as multiple components.

### **BRIEF DESCRIPTION OF THE DRAWINGS**

- 5           Fig. 1 is a schematic cross-sectional view of a normal, healthy human heart shown during systole;
- Fig. 1A is the view of Fig. 1 showing the heart during diastole;
- Fig. 1B is a view of a left ventricle of a healthy heart as viewed from a septum and showing a mitral valve;
- 10           Fig. 2 is a schematic cross-sectional view of a diseased human heart shown during systole;
- Fig. 2A is the view of Fig. 2 showing the heart during diastole;
- Fig. 2B is the view of Fig. 1B showing a diseased heart;
- Fig. 3 is a perspective view of a first embodiment of a cardiac support device
- 15   according to the present invention;
- Fig. 3A is a side elevation view of a diseased heart in diastole with the device of Fig. 3 in place;
- Fig. 4 is a perspective view of a second embodiment of a cardiac support device according to the present invention;
- 20           Fig. 4A is a side elevation view of a diseased heart in diastole with the device of Fig. 4 in place;
- Fig. 5 is a cross-sectional view of a device of the present invention overlying a myocardium and with the material of the device gathered for a snug fit;
- Fig. 6 is an enlarged view of a knit construction of the device of the present
- 25   invention in a rest state;
- Fig. 7 is a schematic view of the material of Fig. 6;
- Fig. 8 is a perspective view of an alternate embodiment of a cardiac support device according to the present invention;
- Fig. 8A is a side elevation view of a diseased heart in diastole with the device
- 30   of Fig. 8 in place;
- Fig. 9 is a perspective view of another embodiment of a cardiac support device according to the present invention; and

Fig. 9A is a side elevation view of a diseased heart with an alternate embodiment of a variable compliance device of Fig. 9 in place.

### DESCRIPTION OF THE PREFERRED EMBODIMENT

#### 5 Healthy Human Heart

With initial reference to Figs. 1 and 1A, a normal, healthy human heart H' is schematically shown in cross-section and will now be described in order to facilitate an understanding of the present invention. In Fig. 1, the heart H' is shown during systole (i.e., high left ventricular pressure). In Fig. 1A, the heart H' is shown during  
10 diastole (i.e., low left ventricular pressure).

The heart H' is a muscle having an outer wall or myocardium MYO' and an internal wall or septum S'. The myocardium MYO' and septum S' define four internal heart chambers including a right atrium RA', a left atrium LA', a right ventricle RV' and a left ventricle LV'. The plane in which the valves separating the  
15 atria and ventricles lie is visible from the exterior of the heart H' and is designated as the valvular annulus VA'. The heart H' has a length measured along a longitudinal axis AA' – BB' from an upper end or base B' to a lower end or apex A'.

The right and left atria RA', LA' reside in an upper portion UP' of the heart H' adjacent the base B'. The right and left ventricles RV', LV' reside in a lower portion  
20 LP' of the heart H' adjacent the apex A'. The ventricles RV', LV' terminate at ventricular lower extremities LE' adjacent the apex A' and spaced therefrom by the thickness of the myocardium MYO'.

Due to the compound curves of the upper and lower portions UP', LP', the upper and lower portions UP', LP' meet at a circumferential groove commonly  
25 referred to as the A-V groove AVG'. Extending away from the upper portion UP' are a plurality of major blood vessels communicating with the chambers RA', RV', LA', LV'. For ease of illustration, only the superior vena cava SVC' and a left pulmonary vein LPV' are shown as being representative.

The heart H' contains valves to regulate blood flow between the chambers  
30 RA', RV', LA', LV' and between the chambers and the major vessels (e.g., the superior vena cava SVC' and a left pulmonary vein LPV'). For ease of illustration, not all of such valves are shown. Instead, only the tricuspid valve TV' between the

right atrium RA' and right ventricle RV' and the mitral valve MV' between the left atrium LA' and left ventricle LV' are shown as being representative.

The valves are secured, in part, to the myocardium MYO' in a region of the lower portion LP' adjacent the A-V groove AVG' and referred to as the valvular annulus VA'. The valves TV' and MV' open and close through the beating cycle of the heart H.

The right and left atria RA' and LA' receive blood from the venous system and the right and left ventricles RV' and LV' pump blood into the arterial system. The right atrium and ventricle RA' and RV' are separated from the left atrium and ventricle LA' and LV' by a muscular wall, or septum S'.

Blood in which the oxygen content has become partially depleted and the carbon dioxide content has increased as a result of tissue metabolism returns to the right atrium RA'. This blood then enters the right ventricle RV', which pumps it into the pulmonary arteries. The pulmonary arteries branch to transport blood to the lungs. The blood that returns to the left atrium LA' by way of the pulmonary veins LPV' is therefore enriched in oxygen. The path of blood from the heart (right ventricle RV') through the lungs, and back to the heart (left atrium LA') is referred to as pulmonary circulation.

Oxygen rich blood in the left atrium LA' enters the left ventricle LV' and is pumped into the aorta. Arterial branches from the aorta supply oxygen rich blood to all of the organ systems and are thus part of the systemic circulation.

Arterial pressure is significantly higher in the systemic circulation than in the pulmonary circulation. Therefore the left ventricle LV' performs more work than the right ventricle RV'. As a result, in healthy hearts, the left ventricle LV' wall is generally about twice as thick as that of the right ventricle RV'.

#### The Cardiac Cycle

The events that occur from the beginning of one heartbeat to the beginning of the next are referred to as the cardiac cycle. Generally, the cardiac cycle includes a period of relaxation called diastole, during which blood flows from the veins into the atria and ventricles, followed by a period of contraction called systole. Figs. 1 and 1A show a normal, healthy heart H' during systole and diastole, respectively. During

systole (Fig. 1), the myocardium MYO' is contracting and the heart assumes a shape including a generally conical lower portion LP'. During diastole (Fig. 1A), the heart H' is expanding and the conical shape of the lower portion LP' bulges radially outwardly (relative to axis AA' – BB').

5           The motion of the heart H' and the variation in the shape of the heart H' during contraction and expansion is complex. The amount of motion varies considerably throughout the heart H'. The motion includes a component which is parallel to the axis AA' – BB' (conveniently referred to as longitudinal expansion or contraction). The motion also includes a component perpendicular to the axis AA'-  
10 BB' (conveniently referred to as circumferential expansion or contraction).

During the initial segment of diastole, blood flows from the veins, directly through the atria and into the ventricles. During the final segment of diastole, the atria contract, causing additional filling of the ventricles. In a typical human heart, the right atrial pressure rises to about 4 to about 6 mmHg during atrial contraction.  
15 In contrast, the left atrial pressure rises to about 7 to about 8 mmHg during atrial contraction.

Immediately after ventricular contraction begins, the ventricular pressure abruptly rises, causing the A-V valves to close. The ventricular pressure then builds up sufficiently to push the semilunar (aortic and pulmonary) valves open against the  
20 pressures in the aorta and pulmonary artery. The ventricular pressures push the semilunar valves open when the left ventricular pressure rises above diastolic aortic pressure, to between about 80 mmHg to 85 mmHg, (and the right ventricular pressure rises above pulmonary artery diastolic pressure, to between about 8 mmHg and 10 mmHg). At the end of systole, ventricular relaxation begins suddenly,  
25 allowing the intraventricular pressures to fall rapidly. The elevated pressures in the distended large arteries immediately push blood back toward the ventricles, which snaps the aortic and pulmonary valves closed. The ventricular muscle continues to relax and the intraventricular pressures fall rapidly back to their low diastolic levels. Then the AV valves open to begin a new cycle.

30

Comparison of a Diseased Heart and a Healthy Heart

Having described a healthy heart H' during systole (Fig. 1) and diastole (Fig. 1A), comparison can now be made with a heart deformed by congestive heart disease. Such a heart H is shown in systole in Fig. 2 and in diastole in Fig. 2A. All  
5 elements of diseased heart H are labeled identically with similar elements of healthy heart H' except only for the omission of the apostrophe in order to distinguish diseased heart H from healthy heart H'.

Comparing Figs. 1 and 2 (showing hearts H' and H during systole), the lower  
10 portion LP of the diseased heart H has lost the tapered conical shape of the lower portion LP' of the healthy heart H'. Instead, the lower portion LP of the diseased heart H bulges outwardly between the apex A and the A-V groove AVG. So deformed, the diseased heart H during systole (Fig. 2) resembles the healthy heart H' during diastole (Fig. 1A). During diastole (Fig. 2A), the deformation is even more extreme.

15 As a diseased heart H enlarges from the representation of Figs. 1 and 1A to that of Figs. 2 and 2A, the heart H becomes a progressively inefficient pump. Therefore, the heart H requires more energy to pump the same amount of blood. Continued progression of the disease results in the heart H being unable to supply adequate blood to the patient's body and the patient becomes symptomatic.

20 For ease of illustration, the progression of congestive heart disease has been illustrated and described with reference to a progressive enlargement of the lower portion LP of the heart H. While such enlargement of the lower portion LP is most common and troublesome, enlargement of the upper portion UP may also occur.

In addition to cardiac insufficiency, the enlargement of the heart H can lead  
25 to valvular disorders. As the circumference of the valvular annulus VA increases, the leaflets of the valves TV and MV may spread apart. After a certain amount of enlargement, the spreading may be so severe the leaflets cannot completely close (as illustrated by the mitral valve MV in Fig. 2A). Incomplete closure results in valvular regurgitation contributing to an additional degradation in cardiac  
30 performance. While circumferential enlargement of the valvular annulus VA may contribute to valvular dysfunction as described, the separation of the valve leaflets is

most commonly attributed to deformation of the geometry of the heart H. This is best described with reference to Figs. 1B and 2B.

Figs. 1B and 2B show a healthy and diseased heart, respectively, left ventricle LV', LV during systole as viewed from the septum (not shown in Figs. 1B and 2B). In a healthy heart H', the leaflets MVL' of the mitral valve MV' are urged closed by left ventricular pressure. The papillary muscles PM', PM are connected to the heart wall MYO', MYO, near the lower ventricular extremities LE', LE. The papillary muscles PM', PM pull on the leaflets MVL', MVL via connecting chordae tendineae CT', CT. Pull of the leaflets by the papillary muscles functions to prevent valve leakage in the normal heart by holding the valve leaflets in a closed position during systole. In the significantly diseased heart H, the leaflets of the mitral valve may not close sufficiently to prevent regurgitation of blood from the ventricle LV to the atrium during systole.

As shown in Fig. 1B, the geometry of the healthy heart H' is such that the myocardium MYO', papillary muscles PM' and chordae tendineae CT' cooperate to permit the mitral valve MV' to fully close. However, when the myocardium MYO bulges outwardly in the diseased heart H (Fig. 2B), the bulging results in displacement of the papillary muscles PM. This displacement acts to pull the leaflets MVL to a displaced position such that the mitral valve cannot fully close.

Having described the characteristics and problems of congestive heart disease, the treatment method and apparatus of the present invention will now be described.

#### Cardiac Support Device

In general, the invention provides a cardiac support device configured to cover at least the left or right ventricular myocardium to constrain against enlargement of the ventricular wall of the heart H without restricting contraction of the heart H during systole.

As used herein, "cover" means that the device is in contact with the cardiac surface and reduces expansion of the heart wall during diastole by applying a constraining force on the surface of the heart. A device that "covers" the lower extremities of the heart may be constructed as a continuous material that can

substantially encircle the external surface of the lower extremities of the heart. In an alternate embodiment, the device is constructed as one or two or more separate components. In one embodiment, the device is constructed from at least one component configured to substantially overly one ventricle of the heart (e.g., extend  
5 from septal wall to septal wall). Alternately, the device may be constructed from one or more components, each of which overly only a segment or piece of a ventricle.

The device 10 is adjusted to a snug fit on the heart H during diastole. Care is taken to avoid tightening the device 10 too much such that cardiac function is  
10 impaired. During diastole, the ventricles fill with blood. If the device 10 is too tight, the ventricles may not adequately expand. During the fitting of the device 10, the surgeon can monitor ventricular pressure, for example, by monitoring pulmonary wedge pressure. While minor increases in pressure (e.g., 2 – 3 mm Hg) can be tolerated, the device 10 is snugly fit on the heart H but not so tight as to cause a  
15 significant increase in left ventricular pressure during diastole.

With reference now to Figs. 3, 3A, 4 and 4A, the device of the present invention is shown to include flexible, biologically compatible material. The device 10 is generally a knit material having upper and lower ends 12, 14. In one embodiment, the device 10, 10' defines an internal volume 16, 16' which is  
20 completely enclosed but for the open ends 12, 12' and 14'. In the embodiment of Fig. 3, lower end 14 the device encloses the apex of the heart. In the embodiment of Fig. 4, lower end 14' is open, i.e., the apex of the heart protrudes beyond the lower end 14' of the device. In both embodiments, upper ends 12, 12' are open. Elements in common between the figures are numbered identically with the occasional  
25 addition of an apostrophe to distinguish one embodiment from another. Such elements need not be separately discussed.

The device 10 is dimensioned with respect to a heart H to be treated. Specifically, the device 10 is sized for expansion of the heart H to be constrained. The device 10 has a length L between the upper and lower ends 12, 14 sufficient for  
30 the device 10 to constrain the left or right (or both) ventricular lower extremities of the heart H. The upper end 12 of the jacket 10 extends up to, and if desired, to include, the valvular annulus VA. Where it is desired to constrain enlargement of



the upper portion UP, the device 10 may be extended to cover the upper portion UP. In a preferred embodiment, the device 10 is sized so that the upper end 12 can reside in the A-V groove AVG.

Sizing the device 10 for the upper end 12 to terminate at the A-V groove  
5 AVG is desirable for a number of reasons. First, the groove AVG is a readily identifiable anatomical feature to assist a surgeon in placing the device 10. By placing the upper end 12 in the A-V groove AVG, the surgeon is assured the device 10 will provide sufficient support at the valvular annulus VA. The A-V groove AVG and the major vessels act as natural stops for placement of the device 10 while  
10 assuring coverage of the valvular annulus VA. Using such features as natural stops is particularly beneficial in minimally invasive surgeries where a surgeon's vision may be obscured or limited.

After the device 10 is positioned on the heart H as described above, the device 10 is secured to the heart. Preferably, the device 10 is secured to the heart H  
15 through sutures. The device 10 is sutured to the heart H at suture locations 15 circumferentially spaced along the upper end 12 and along or proximate the septal wall.

To permit the device 10 to be easily placed on the heart H, the material of the device 10 is preferably larger than the lower portion LP of the heart H during  
20 diastole. So sized, the device 10 may be easily applied to the heart H. Once secured, the device 10 may be adjusted to snugly conform to the external geometry of the heart H during diastole. Such sizing is easily accomplished due to the knit construction of the device 10. For example, excess material of the jacket 10 can be gathered and sutured S" (Fig. 5) to reduce the maximum diastolic volume and  
25 conform the material to the shape of the heart H during diastole. As an alternative to gathering the material, the tension of the material can be adjusted using other methods discussed below.

#### Variable Compliance

30 The device 10 described above is configured to surround at least parts of the left and/or right ventricular chambers to provide support at end diastole to reduce dilation associated with heart failure. According to one embodiment of the

invention, the device 10 may be constructed such that pressure exerted by the device on one ventricle is different than the pressure exerted by the device on the other ventricle.

In a preferred embodiment, the device 10 of the present invention takes into  
5 consideration the physiological differences between the right and left ventricles RV and LV (i.e., the right ventricular wall is generally about half the thickness of the left ventricular wall and the pressure in the right ventricle is substantially lower than that of the left ventricle). Because excess pressure on the right ventricle RV may prevent filling of the right ventricle RV, the pressure exerted by the device on the right  
10 ventricle RV is preferably less than the end diastolic pressure of the right ventricle RV.

Generally, the end diastolic pressure of the left ventricle is higher than the end diastolic pressure of the right ventricle. For example, in a healthy heart, the end diastolic pressure of the left ventricle is between about 6 mmHg and about 8 mmHg  
15 whereas the end diastolic pressure of the right ventricle is between about 4 mmHg and about 6 mmHg. Generally, in a healthy heart, the end systolic pressure of the left ventricle is between about 100 mmHg and about 120 mmHg and the end systolic pressure of the right ventricle is between about 18 mmHg and about 24 mmHg. Generally, the end diastolic in both the right and left ventricle and atria are higher in  
20 a diseased heart H than in a healthy heart H'.

The invention provides a device 10 in which the pressure exerted by the device 10 on the right ventricle RV may be different (e.g., less) than the pressure exerted by the device 10 on the left ventricle LV. Preferably the pressure differential is feasible because the material of the device 10 is secured to the cardiac surface.  
25 Although the material can be secured anywhere on the cardiac surface, the material is preferably secured at a location at or proximate the septal wall that separates the two ventricles. Preferably, the material is secured via sutures that extend through the myocardium, preferably the suture extend through the ventricle wall.

Attachment of the material to the cardiac surface helps disconnect the applied  
30 ventricular pressure and tension in the material covering each ventricle such that the right ventricle and left ventricle can achieve different diastolic pressures. Because the left ventricle typically expands at a higher pressure than the right ventricle, a

cardiac support device (which defines a specific volume) implanted without attachment to the cardiac surface (i.e., proximate the septal wall) may result in left ventricle filling at the expense of right ventricle expansion. Such as "volume shift" could occur even with a device constructed wherein the material configured to cover the right ventricle has a different compliance than the material configured to cover the left ventricle. However, a cardiac support device constructed wherein the material designed to cover the right ventricle has a different compliance than the material designed to cover the left ventricle is implanted without septal attachment may still be desirable. Although such an embodiment may not initially address the "volume shift" phenomenon, once fibrosis secures the material in place on the cardiac surface, the differing compliance in the fabric would allow different filling profiles for each ventricle.

The device may be installed as a single unitary "jacket" configured to cover both the right and left ventricles or as one or two or more separate components (e.g., a first component configured to cover the right ventricle and a second component configured to cover the left ventricle). Generally, for a unitary device, a conical jacket is first positioned over the heart. At this time it may be desirable to anchor the device in a few locations around the base of the heart. The device is then secured to the heart, preferably proximate the septal line. Once secured to the heart, the tension of the material covering each ventricle may be adjusted. The tension of the material covering the right ventricle can be lower than the tension of the material covering the left, if desired. If desired, the device can be further anchored by placing additional sutures at the base.

Alternately, the device can be installed as two or more separate components. According to one embodiment, a first component (e.g., a piece of material) having a preselected size is positioned over a first ventricle. Lateral edges of the material are attached to the cardiac surface, preferably by sutures that extend through the myocardium, most preferably at or proximate the septal wall. The top and bottom of the material are also sutured to the cardiac surface. If desired, a second component (e.g., a second piece of material) having a preselected size may be positioned over the remaining ventricle and secured in a similar manner. In one embodiment, the device may be implanted only over left ventricle, leaving the right ventricle

unrestricted, for example, to constrain left ventricular expansion. Alternately, it may be desirable to constrain the expansion of only the right ventricle, for example, an infarcted right ventricle RV' to prevent aneurysm of the right side, while not restraining the left ventricle LV' (e.g., if the left ventricle is healthy). In a further  
5 embodiment, the device may comprise a plurality of components. For example, one ventricle (right or left, or both) may be covered with one or more pieces of material, each having the same or different compliance.

The device 10 can be secured to the septal wall, or proximate the septal wall, using a variety of methods, including sutures, staples and adhesives. Actual  
10 attachment may be into or through the septal wall S' or into or through the left ventricle LV' near the septum. Typically, the device 10 is secured to the septal wall using sutures. In one embodiment, the knit material of the device 10 is sutured directly to the septal wall S'. (See Figs. 3A and 4A) Alternately, the knit material of the device 10 may be secured to a securing member that is then secured to the septal  
15 wall. In one embodiment, the securing member is an inelastic band 40 that is secured to the septal wall (See Fig. 8A). In another embodiment, the knit material of the device 10 is secured to rings 50 of a material, for example, plastic, metal or fabric rings 50, wherein the rings 50 are then secured to the septal wall (See Fig. 9A).

20 The pressure differential between the material covering the right and left ventricles can be achieved in a variety of ways. In one embodiment of the invention, the pressure differential is achieved by constructing the device using two types of material, one with a higher compliance than the other. A first piece of material is secured along or proximate the septal wall to cover one ventricle and a second piece  
25 of material is secured along or proximate the septal wall to cover a second ventricle.

According to one embodiment, the material covering the right ventricle RV is more compliant than the material covering the left ventricle LV. As used herein, the term "compliant" refers to a material that can expand in response to a force. "Compliance" refers to the displacement (in inches or centimeters) or strain  
30 (inches/inch or cm/cm) per a unit load (in pounds or kilograms) or load per unit width (in pounds per inch or kilograms per centimeter) for a material. A material that is more compliant is displaced further per unit load than a material that is less

compliant. The compliance of the material may be due to a variety of factors, including, but not limited to, the compliance of the individual filaments 30 that make up the fibers 20, the relative movement of the filaments 30 within a fiber 20, and/or the relative movement of the intertwined fibers 20 when subjected to load. (See Fig.

5 6)

In one embodiment of the invention, the material covering the right ventricle is more compliant than the material covering the left ventricle. For example, the multiaxial expansion of the material covering the right ventricle may be between about 20% and 30% when exposed to a load between about 1 pounds per inch (1.8  
10 N/cm) and about 3 pounds per inch (5 N/cm) whereas the material covering the left ventricle may have a multiaxial expansion between about 10% and 20% when exposed to the same load.

The term "multiaxial expansion" refers expansion of a material along at least a first and a second axis and includes expansion along more than two axes.

15 In another embodiment, the pressure differential is achieved by having the tension of the material covering the left ventricle LV greater than the tension of the material covering the right ventricle RV. The tension of the material can be modified using a variety of methods. In one embodiment, various sized materials are prepared such that different sized pieces of material are used for different  
20 predetermined cardiac expansion sizes or expansion ranges. "Predetermined size" refers to the predetermined expansion limit of the material that circumferentially constrains cardiac expansion during diastolic filling of the heart.

Alternately, the material can include a mechanism for selectively adjusting the size of the material. Advantageously, such an adjustment mechanism can be  
25 used initially to set the tension of the material covering each ventricle, and also subsequently to readjust the amount of cardiac reinforcement as therapeutic reduction of cardiac expansion occurs. In one embodiment, the material covering one or both of the ventricles can be gathered and secured, for example, by suturing. (See Figure 5)

30 According to another embodiment, an inflatable member is mounted between the material covering one of the ventricles and the epicardium. A separate inflatable member can be mounted between the material covering the other ventricle if desired.

Alternately, an inflatable member may only be mounted between the material covering one ventricle and the ventricular epicardium. Inflating the inflatable member through an inflation port with, for example, a gas or a liquid can increase the tension of the material. Inflation of the inflatable member provides an increase  
5 in the tension of the material covering the ventricle.

Another mechanism for selectively adjusting the tension of the material can include a slot that opens at the base of the jacket and extends towards the apex. The slot includes opposing lateral edges. By adjusting the proximity of the opposing lateral edges, the tension of the material can be varied. Moving the opposing edges  
10 of the slot closer together narrows the slot and increases the material tension. The opposing edges of the slot can be fastened together at a predetermined proximity by, for example, one or more lateral attachment devices, such as a cord, suture, band, adhesive or shape memory element attached to each lateral edge.

#### 15 Material

As mentioned, the jacket 10 is constructed from a knit, biocompatible material. The knit 18 is illustrated in Fig. 6. Preferably, the knit is a so-called "Atlas knit" well known in the fabric industry. The Atlas knit is described in Paling, Warp Knitting Technology, p. 111, Columbine Press (Publishers) Ltd., Buxton,  
20 Great Britain (1970).

The Atlas knit is a knit of fibers 20 having directional expansion properties. More specifically, the knit 18, although formed of generally inelastic fibers 20, permits a construction of a flexible fabric at least slightly expandable beyond a rest state. Fig. 6 illustrates the knit 18 in a rest state. The fibers 20 of the fabric 18 are  
25 woven into two sets of fiber strands 21a, 21b having longitudinal axes  $X_a$  and  $X_b$ . The strands 21a, 21b are interwoven to form the fabric 18 with strands 21a generally parallel and spaced-apart and with strands 21b generally parallel and spaced-apart.

For ease of illustration, fabric 18 is schematically shown in Fig. 7 with the axis of the strands 21a, 21b only being shown. The strands 21a, 21b are interwoven  
30 with the axes  $X_a$  and  $X_b$  defining a diamond-shaped open cell 23 having diagonal axes  $A_m$ . In a preferred embodiment, the axes  $A_m$  are 5 mm in length when the fabric 18 is at rest and not stretched. The fabric 18 can stretch in response to a force. For

any given force, the fabric 18 stretches most when the force is applied parallel to the diagonal axes  $A_m$ . The fabric 18 stretches least when the force is applied parallel to the strand axes  $X_a$  and  $X_b$ . The jacket 10 is constructed for the material of the knit to be directionally aligned for a diagonal axis  $A_m$  to be parallel to the heart's

5 longitudinal axis AA-BB

While the jacket 10 is expandable due to the above described knit pattern, the fibers 20 of the knit 18 are preferably non-expandable. While all materials expand to at least a small amount, the fibers 20 are preferably formed of a material with a low modulus of elasticity. In response to the low pressures in the heart H during

10 diastole, the fibers 20 are non-elastic. In a preferred embodiment, the fibers are 70 Denier polyester. While polyester is presently preferred, other suitable materials include polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE), polypropylene and stainless steel.

The knit material has numerous advantages. Such a material is flexible to

15 permit unrestricted movement of the heart H (other than the desired support on circumferential expansion). The material is open defining a plurality of interstitial spaces for fluid permeability as well as minimizing the amount of surface area of direct contact between the heart H and the material of the jacket 10 (thereby minimizing areas of irritation or abrasion) to minimize fibrosis and scar tissue.

20 The open areas of the knit construction also allows for electrical connection between the heart and surrounding tissue for passage of electrical current to and from the heart. For example, although the knit material is an electrical insulator, the open knit construction is sufficiently electrically permeable to permit the use of trans-chest defibrillation of the heart. Also, the open, flexible construction permits

25 passage of electrical elements (e.g., pacer leads) through the jacket. Additionally, the open construction permits other procedures, e.g., coronary bypass, to be performed without removal of the jacket.

A large open area for cells 23 is desirable to minimize the amount of surface area of the heart H in contact with the material of the jacket 10 (thereby reducing

30 fibrosis). However, if the cell area 23 is too large, localized aneurysm can form. Also, a strand 21a, 21b can overly a coronary vessel with sufficient force to partially block the vessel. A smaller cell size increases the number of strands thereby

decreasing the restricting force per strand. Preferably, a maximum cell area is no greater than about 9 mm<sup>2</sup> (about 3 mm by 3 mm) and, more preferably, is about 5.8 mm<sup>2</sup> (about 2.4 mm by 2.4 cm). The maximum cell area is the area of a cell 23 after the material of the jacket 10 is fully stretched and adjusted to the maximum adjusted  
5 volume on the heart H as previously described.

The fabric 18 is preferably tear and run resistant. In the event of a material defect or inadvertent tear, such a defect or tear is restricted from propagation by reason of the knit construction.

With the foregoing, a device and method have been taught to treat cardiac  
10 disease. The jacket 10 constrains further undesirable circumferential enlargement of the heart while not impeding other motion of the heart H. With the benefits of the present teachings, numerous modifications are possible. For example, the jacket 10 need not be directly applied to the epicardium (i.e., outer surface of the myocardium) but could be placed over the parietal pericardium. Further, an anti-fibrosis lining  
15 (such as a PTFE coating on the fibers of the knit) could be placed between the heart H and the jacket 10. Alternatively, the fibers 20 can be coated with PTFE.

The jacket 10 is low-cost, easy to place and secure, and is susceptible to use in minimally invasive procedures. The thin, flexible fabric 18 permits the jacket 10 to be collapsed and passed through a small diameter tube in a minimally invasive  
20 procedure.

The jacket 10 can be used in early stages of congestive heart disease. For patients facing heart enlargement due to viral infection, the jacket 10 permits support of the heart H for a sufficient time to permit the viral infection to pass. In addition to preventing further heart enlargement, the jacket 10 treats valvular disorders by  
25 constraining circumferential enlargement of the valvular annulus and deformation of the ventricular walls.

The jacket 10, including the knit construction, freely permits longitudinal and circumferential contraction of the heart H (necessary for heart function). Unlike a solid wrap (such as a muscle wrap in a cardiomyoplasty procedure), the fabric 18  
30 does not impede cardiac contraction. After fitting, the jacket 10 is inelastic to prevent further heart enlargement while permitting unrestricted inward movement of the ventricular walls. The open cell structure permits access to coronary vessels for



bypass procedures subsequent to placement of the jacket 10. Also, in cardiomyoplasty, the latissimus dorsi muscle has a variable and large thickness (ranging from about 1 mm to 1 cm). The material of the jacket 10 is uniformly thin (less than 1 mm thick). The thin wall construction is less susceptible to fibrosis and  
5 minimizes interference with cardiac contractile function.

In addition to the foregoing, the present invention can be used to reduce heart size at the time of placement in addition to preventing further enlargement. For example, the device can be placed on the heart and sized snugly to urge the heart to a reduced size. More preferably, the heart size can be reduced at the time of jacket  
10 placement through drugs (e.g., dobutamine, dopamine or epinephrine or any other positive inotropic agents) to reduce the heart size. The jacket of the present invention is then snugly placed on the reduced sized heart and prevents enlargement beyond the reduced size.

From the foregoing, a low cost, reduced risk method and device are taught to  
15 treat cardiac disease. The invention is adapted for use with both early and later stage congestive heart disease patients. The invention reduces the enlargement rate of the heart as well as reducing cardiac valve regurgitation.

What is claimed is:

1. A device for treating cardiac disease of a heart having a longitudinal axis from an apex to a base, an upper portion and a lower portion divided by an A-V groove, a valvular annulus adjacent said A-V groove, and ventricular lower extremities adjacent said apex, said ventricular lower extremities comprising a right ventricle and left ventricle wherein said right and left ventricle are separated by a septum, the device comprising:
  - flexible material of knit construction having upper and lower ends dimensioned to cover at least said left ventricle or at least said right ventricle; said material adapted to be adjusted on said heart to snugly conform to an external geometry of said heart and constrain circumferential expansion of at least said left ventricle or at least said right ventricle during diastole and permit substantially unimpeded contraction of said heart during systole, wherein pressure exerted by said device on said right ventricle during diastole is different than pressure exerted by said device on said left ventricle during diastole.
2. The device of claim 1, wherein said material is adapted to be secured to said heart proximate said septum.
3. The device of claim 1, wherein said material is secured to said heart by fibrosis.
4. The device of claim 1, wherein said device covers said left and right ventricle.
5. The device of claim 4, wherein said device is constructed as a unitary jacket.

6. The device of claim 4, wherein said device comprises a first component comprising material configured to cover said left ventricle and a second component comprising material configured to cover said right ventricle, wherein said first and second components are implanted separately.
- 5
7. The device of claim 4, wherein said material covering said right ventricle has a greater compliance than said material covering said left ventricle.
8. The device of claim 4, wherein said material covering said left ventricle is under more tension than said material covering said right ventricle.
- 10
9. The device of claim 1, further comprising at least one adjustment mechanism configured to adjust a tension of said material.
- 15
10. The device of claim 4, further comprising a first adjustment mechanism configured to adjust a tension of said material covering said right ventricle and a second adjustment mechanism configured to adjust a tension of said material covering said left ventricle, wherein the tension of the material covering said left ventricle is greater than the tension of the material covering said right ventricle.
- 20
11. The device of claim 7, wherein said adjustment mechanism comprises material that is sufficiently flexible such that excess amounts of said material can be gathered following placement of said material over said heart to snugly conform said material to an external geometry of said heart.
- 25
12. The device of claim 9, wherein said adjustment mechanism comprises a slot comprising opposing lateral edges, wherein the tension of said material is adjusted by adjusting a proximity of said opposing lateral edges.
- 30
13. The device of claim 9, wherein said adjustment mechanism comprises an inflatable member mounted between said material and the heart.

14. The device of claim 1, further comprising a securing member.
15. The device of claim 14, wherein said securing member comprises an inelastic  
5 band configured to extend along said septum when said device is in place.
16. The device of claim 14, wherein said securing member comprises a plurality  
of rings configured to extend along said septum when said device is in place.
- 10 17. A device according to claim 1 wherein said material is dimensioned to have a  
longitudinal dimension between said upper and lower ends sufficient for said  
jacket to constrain said valvular annulus.
18. A device according to claim 1 wherein said material encloses said apex.  
15
19. A device according to claim 1 wherein said apex protrudes beyond said  
material.
20. A device according to claim 1 wherein said jacket is sized to at least partially  
20 cover and constrain said upper portion.
21. A method for treating cardiac disease of a patient's heart, said heart having a  
longitudinal axis from an apex to a base, an upper portion and a lower  
portion divided by an A-V groove, a valvular annulus adjacent said A-V  
25 groove, and ventricular lower extremities adjacent said apex, said ventricular  
lower extremities comprising a right ventricle and left ventricle wherein said  
right and left ventricle are separated by a septum, said method comprising:  
surgically accessing said patient's heart;  
30

positioning material over at least said left ventricle or at least said right ventricle, said material comprising a biomedical material having an upper end and a lower end;

5       securing said upper end of said material to said heart; and

adjusting said material on said heart to snugly conform to an external geometry of said heart to constrain circumferential expansion of said heart during diastole and permit unimpeded contraction of said heart during  
10       systole, wherein pressure exerted by said device on said right ventricle during diastole is different than pressure exerted by said device on said left ventricle during diastole.

22.       The method of claim 21, further comprising securing said material proximate  
15       said septum.

23.       The method of claim 21, further comprising positioning material over both said right and left ventricles.

20       24.       The method of claim 21, wherein said right ventricle is not constrained.

25.       The method of claim 21, wherein said left ventricle is not constrained.

26.       The method of claim 21, further comprising providing a unitary device  
25       comprising material configured to cover both said right and left ventricles.

27.       The method of claim 23, further comprising adjusting a tension of said material covering said left ventricle by gathering excess material and suturing a seam on said material covering said left ventricle.

30

28. The method of claim 23, further comprising adjusting a tension of said material covering said right ventricle by gathering excess material and suturing a seam on said material covering said right ventricle.
- 5 29. The method of claim 23, wherein said tension of said material covering said left ventricle is greater than said tension of said material covering said right ventricle.
- 10 30. A method for treating cardiac disease of a patient's heart, said heart having a longitudinal axis from an apex to a base, an upper portion and a lower portion divided by an A-V groove, a valvular annulus adjacent said A-V groove, and ventricular lower extremities adjacent said apex, said ventricular lower extremities comprising a right ventricle and left ventricle wherein said right and left ventricle are separated by a septum, said method comprising:
- 15 surgically accessing said patient's heart;
- positioning a first component over a first ventricle, said first component comprising a piece of biomedical material having an upper end and a lower end;
- 20 securing said first component proximate said septum;
- securing said upper end of said material of said first component to said heart;
- 25 adjusting said first component to snugly conform to an external geometry of said heart and assume a maximum adjusted volume for said material to constrain circumferential expansion of said first ventricle beyond said maximum adjusted volume during diastole and permitting unimpeded
- 30 contraction of said heart during systole;

positioning a second component over a second ventricle, said second component comprising a piece of biomedical material having an upper end and a lower end;

5       securing said second component proximate said septum;

securing said upper end of said second component to said heart; and

10       adjusting said second component to snugly conform to an external geometry of said second ventricle and assume a maximum adjusted volume for said material to constrain circumferential expansion of said heart beyond said maximum adjusted volume during diastole and permitting unimpeded contraction of said heart during systole.

15

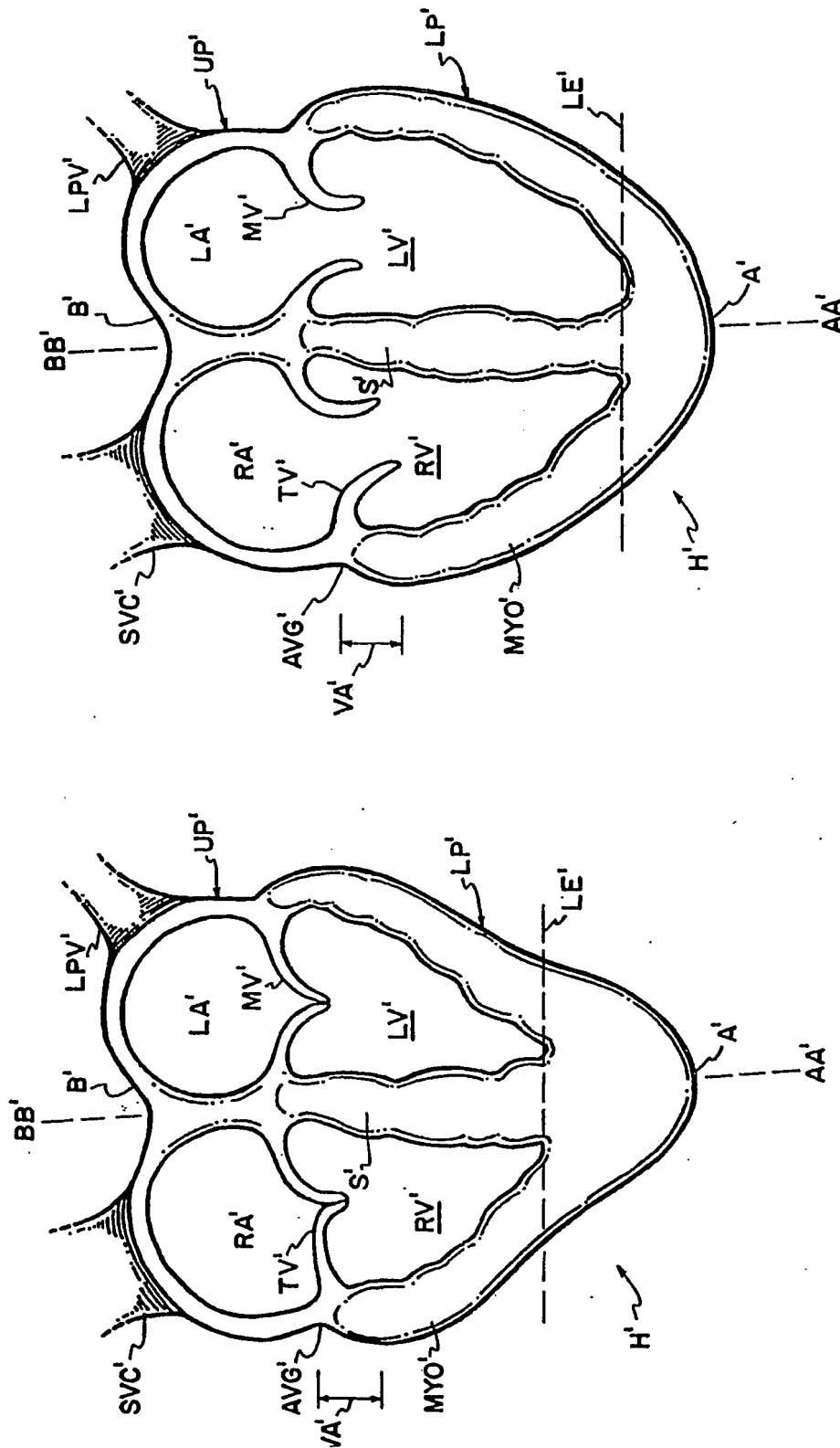
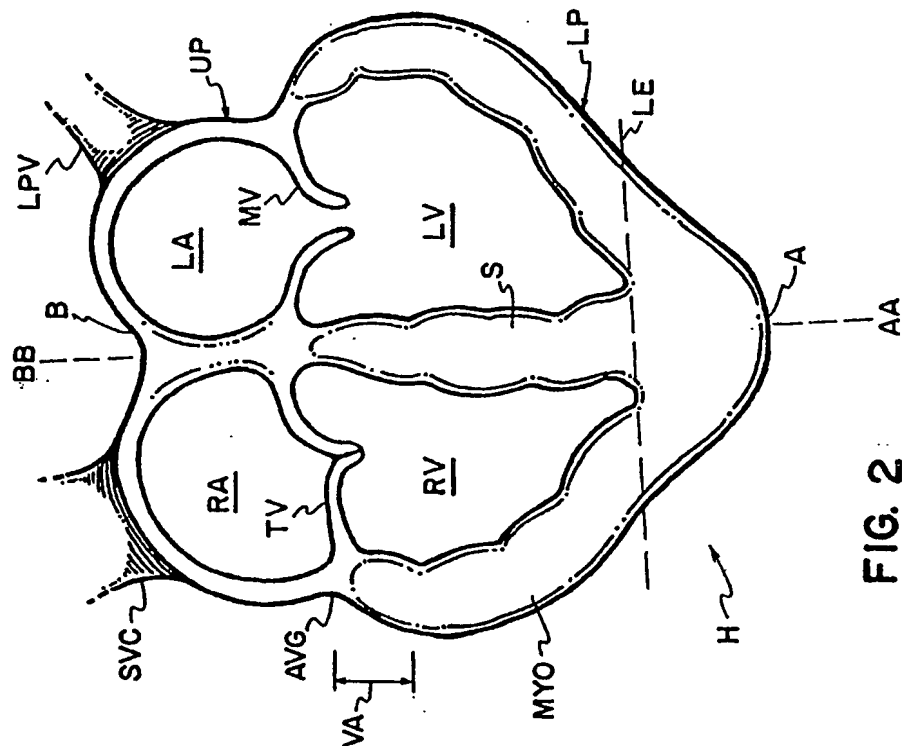
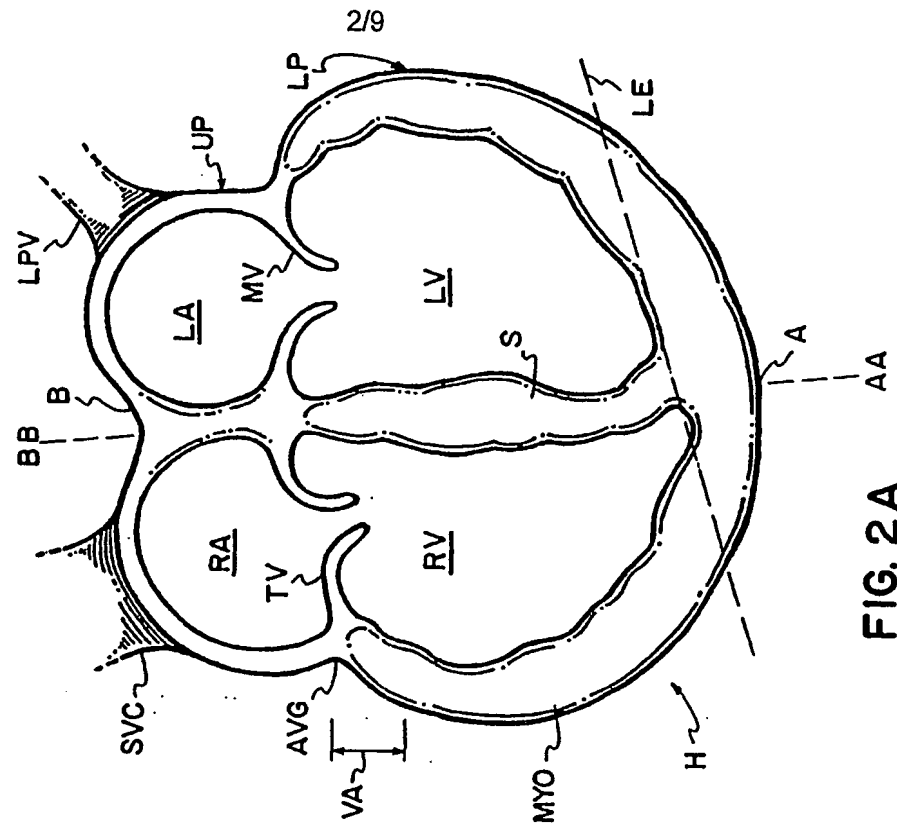
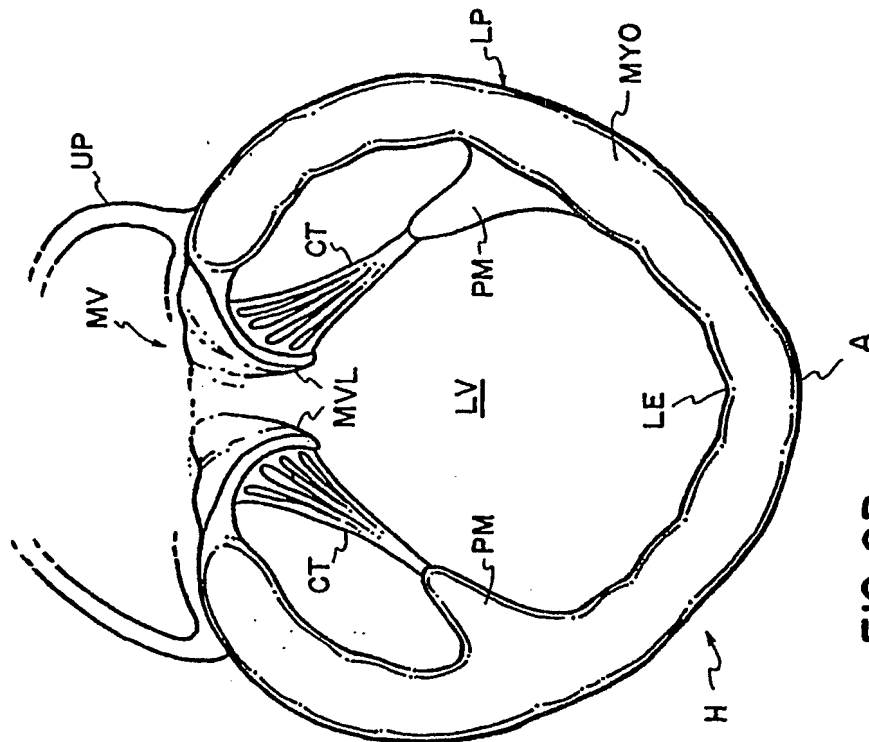


FIG. 1A

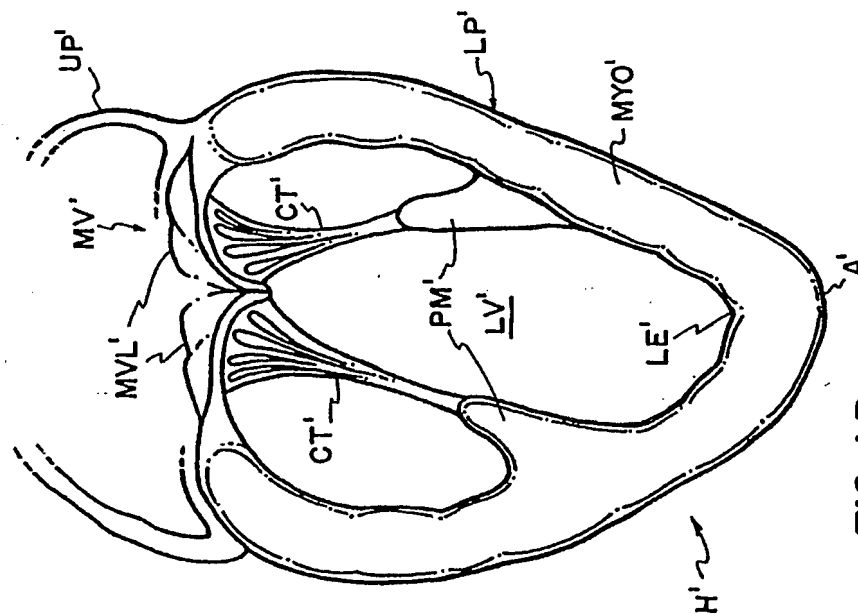
FIG. I







**FIG. 2B**



**FIG. 1B**

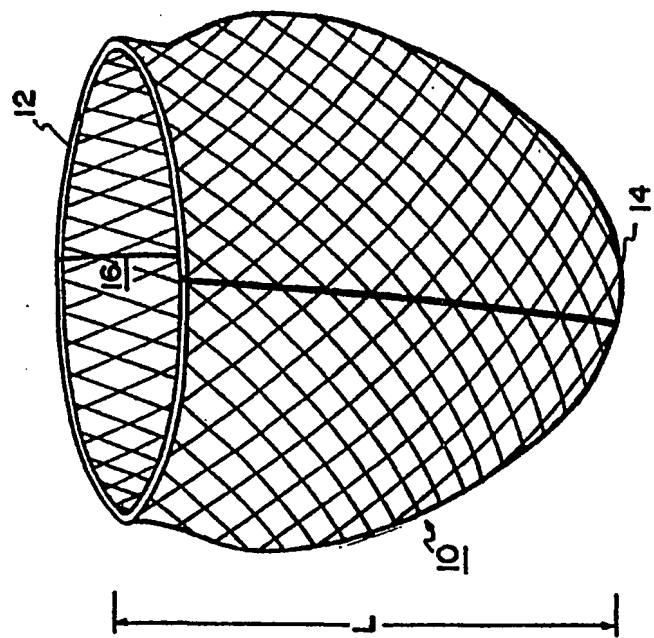
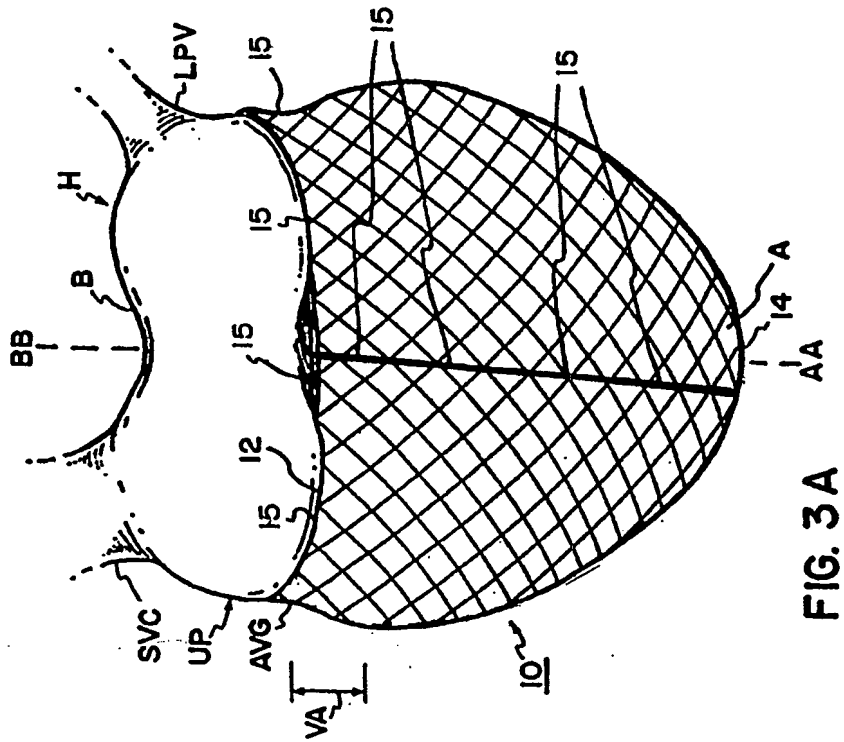


FIG. 3A

FIG. 3

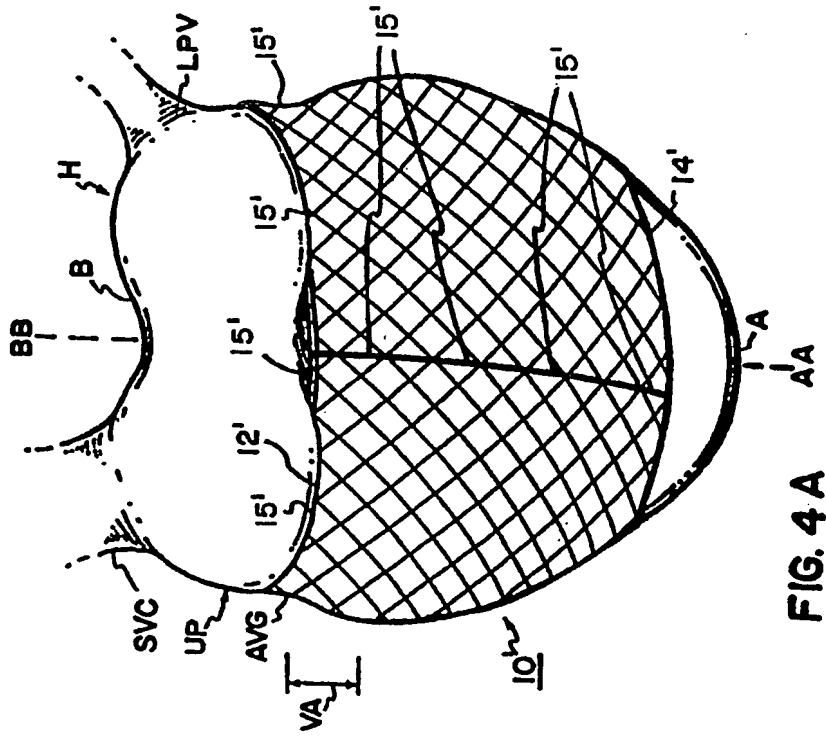


FIG. 4A

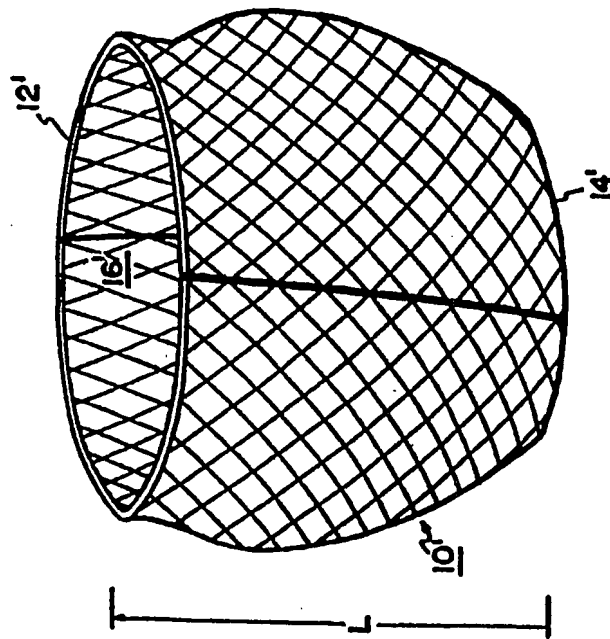


FIG. 4

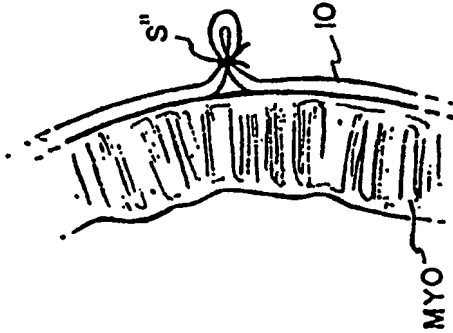


FIG. 5

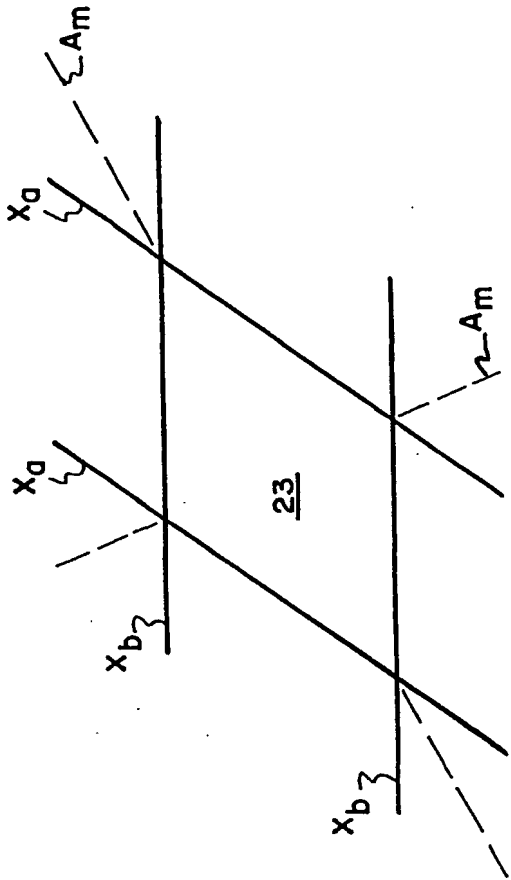
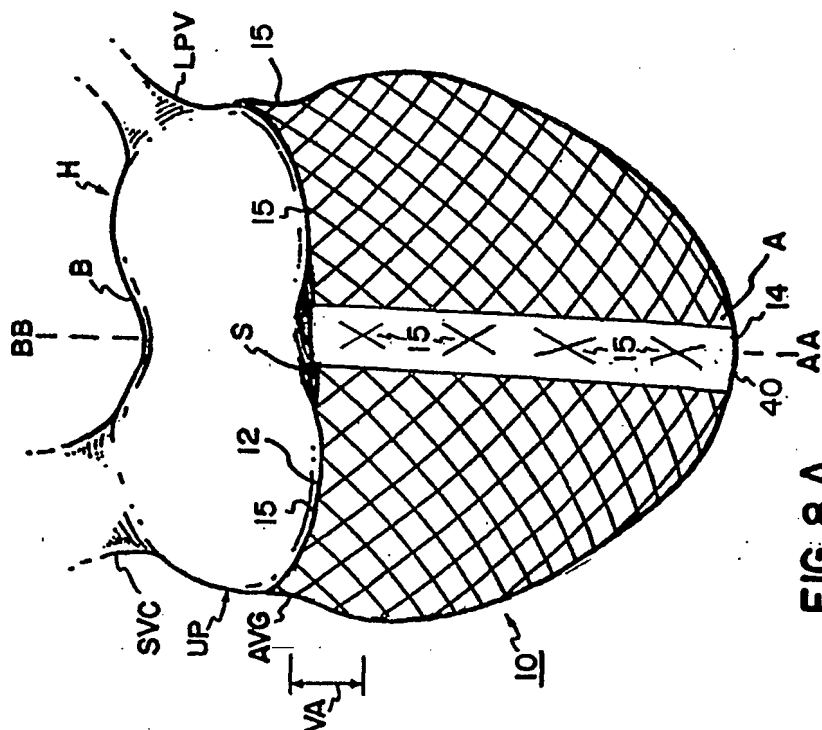
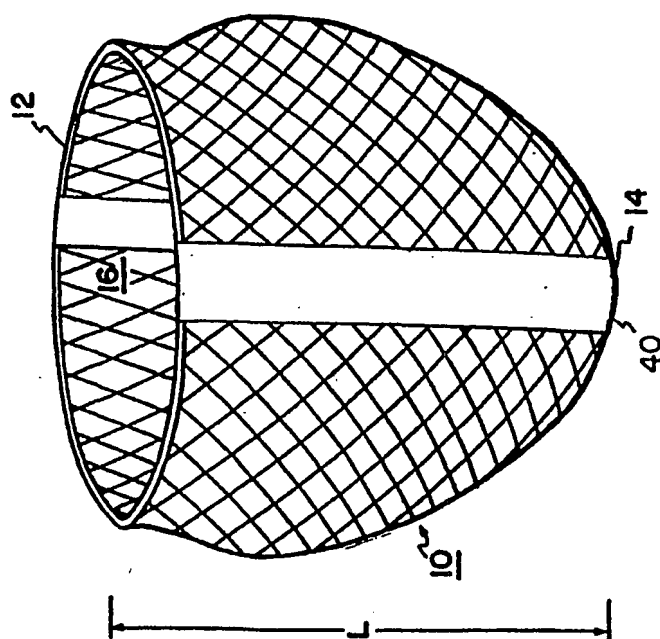


FIG. 7



**FIG. 8 A**



8.6.3

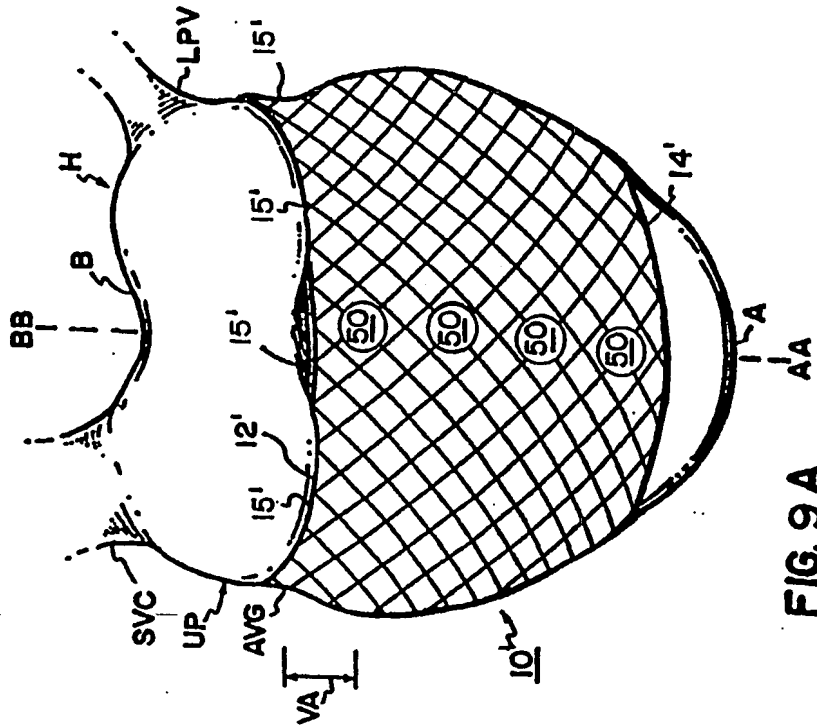


FIG. 9A

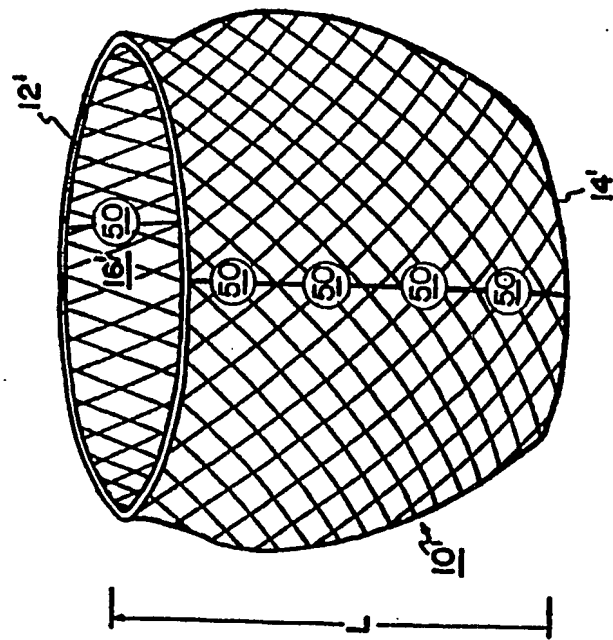


FIG. 9

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**WO 02/11625 A2**

(54) Title: PERCUTANEOUS TRANSLUMINAL MYOCARDIAL IMPLANTATION DEVICE AND METHOD

(57) Abstract:



## PERCUTANEOUS TRANSLUMINAL MYOCARDIAL IMPLANTATION DEVICE AND METHOD

### Field of the Invention

5       The present invention relates generally to devices and methods for increasing the blood pumping efficiency of a heart muscle. More particularly, the present invention relates to devices and methods for treating a heart including one or more areas of non-contracting myocardial tissue that are causing low output ejection fraction.

### 10       Background of the Invention

      The blood pumping action of the heart muscle is critical to sustaining the life of a patient. One condition that is likely to reduce the blood pumping efficiency of the heart muscle is ventricular dilation. When ventricular dilation occurs a ventricle chamber (commonly the left ventricular chamber) becomes enlarged. As the chamber becomes  
15   enlarged, the internal surface area of the chamber increases rapidly. Blood flowing within the heart applies pressure to the internal surface of the heart chamber. Because the blood applies pressure inside the heart chamber across an increased surface area, the force which must be produced by the heart in order to pump blood also increases. In many cases, the cardiac disease which caused the ventricular dilation also limits the  
20   ability of the heart muscle to produce the increased force required to efficiently pump blood. In many cases, the dilation of the heart chamber becomes progressively worse, and the blood pumping efficiency of the heart muscle progressively declines. Ultimately, ventricular dilation may result in heart failure.

In order for the heart to function properly the tissues of the heart muscle must be continuously supplied and re-supplied with oxygen. To receive an adequate supply of oxygen, the heart muscle must be well perfused with blood. If the flow of blood to a portion of the heart muscle is interrupted or diminished, that portion of the heart muscle  
5 may stop contributing to the blood pumping action of the heart muscle.

In a healthy heart, blood perfusion is accomplished with a system of blood vessels and capillaries. However, it is common for the blood vessels to become occluded (blocked) or stenotic (narrowed). A stenosis may be formed by an atheroma that is typically a harder, calcified substance that forms on the walls of a blood vessel.

10 Historically, individual stenotic lesions have been treated with a number of medical procedures including coronary bypass surgery, angioplasty, and atherectomy. Coronary bypass surgery typically involves utilizing vascular tissue from another part of the patient's body to construct a shunt around the obstructed vessel. Angioplasty techniques such as percutaneous transluminal angioplasty (PTA) and percutaneous  
15 transluminal coronary angioplasty (PTCA) are relatively non-invasive methods of treating a stenotic lesion. These angioplasty techniques typically involve the use of a guidewire and a balloon catheter. In these procedures, a balloon catheter is advanced over a guidewire such that the balloon is positioned proximate a restriction in a diseased vessel. The balloon is then inflated and the restriction in the vessel is opened. A third  
20 technique that may be used to treat a stenotic lesion is atherectomy. During an atherectomy procedure, the stenotic lesion is mechanically cut or abraded away from the blood vessel wall.

Coronary by-pass, angioplasty, and atherectomy procedures have all been found effective in treating individual stenotic lesions in relatively large blood vessels. However, the heart muscle is perfused with blood through a network of small vessels and capillaries. In some cases, a large number of stenotic lesions may occur in a large  
5 number of locations throughout this network of small blood vessels and capillaries. The torturous path and small diameter of these blood vessels limit access to the stenotic lesions. The sheer number and small size of these stenotic lesions make techniques such as cardiovascular by-pass surgery, angioplasty, and atherectomy impractical

When techniques that treat individual lesion are not practical other techniques of  
10 improving the oxygenation of myocardial tissue may be utilized. One technique of improving the oxygenation of myocardial tissue is known as percutaneous myocardial revascularization (PMR). A PMR procedure generally involves the creation of holes, craters or channels directly into the myocardium of the heart. PMR was inspired in part by observations that reptilian heart muscles are supplied with oxygen primarily by blood  
15 perfusing directly from within heart chambers to the heart muscle. This contrasts with the human heart, which is supplied by coronary vessels receiving blood from the aorta. Positive clinical results have been demonstrated in human patients receiving PMR treatments. These results are believed to be caused in part by blood flowing within a heart chamber through channels in myocardial tissue formed by PMR. Increased blood  
20 flow to the myocardium is also believed to be caused in part by the healing response to wound formation. Specifically, the formation of new blood vessels is believed to occur in response to the newly created wound. This response is sometimes referred to as angiogenesis. In addition to promoting increased blood flow, it is also believed that PMR

improves a patient's condition through denervation. Denervation is the elimination of nerves. The creation of wounds during a PMR procedure results in the elimination of nerve endings which were previously sending pain signals to the brain as a result of hibernating tissue.

5

### Summary of the Invention

The present invention relates generally to devices and methods for increasing the volume of blood pumped by a heart muscle. More particularly, the present invention relates to devices and methods for treating a heart including one or more areas of non-  
10 contracting myocardial tissue that are causing low output ejection fraction. A therapeutic catheter in accordance with the present invention includes a distal end, a proximal end, and an elongate shaft defining a lumen. A hub is disposed about the elongate shaft proximate it's proximal end and a cutter is fixed to the elongate shaft proximate it's distal end. The cutter includes a distal edge and a cutter lumen.

15 The therapeutic catheter also includes a mooring member disposed at a distal end of a mooring shaft. In a preferred embodiment, the mooring shaft is slidably disposed within the lumen of the elongate shaft and cutter lumen of the cutter. A knob is fixed to a proximal end of the mooring shaft. In a preferred embodiment, the knob is adapted to be rotated by the fingers of a physician. In this preferred embodiment, the rotary motion of  
20 the knob is transferred to the mooring member via the mooring shaft.

A trocar in accordance with the present invention includes a body defining a trocar lumen. The body of the trocar includes a flange, a penetrating portion, a distal end, and a proximal end. A proximal aperture of the trocar is in fluid communication with the

trocar lumen. In a preferred embodiment, the trocar lumen of the trocar is adapted to receive the therapeutic catheter. In a preferred method in accordance with the present invention, the distal end of the therapeutic catheter is inserted into the trocar lumen through the proximal aperture.

5           A guide catheter in accordance with the present invention includes an elongate tubular member defining a central lumen. A plurality of moorings are disposed proximate a distal end of the guide catheter. In one method in accordance with the present invention, the moorings may be utilized to retain the distal end of the guide catheter proximate a donee site. In a preferred embodiment, each mooring comprises a  
10 vacuum orifice. In this preferred embodiment, each vacuum orifice is in fluid communication with a vacuum lumen defined by the elongate tubular member of the guide catheter.

Other embodiments of the moorings are possible without deviating from the spirit or scope of the present invention. For example, each mooring may be comprised of an  
15 elongate wire with a helix disposed proximate its distal end. The helical end of the elongate wire may be "threaded" into the tissue proximate the donee site by rotating the wire. Additional examples, of moorings that may be appropriate in some applications include hooks and barbs.

A method in accordance with the present invention may include the step of  
20 penetrating the skin of a patient with a trocar near a donor site. In a preferred method, the donor site includes muscle tissue. Examples of donor sites that may be suitable in some applications include arms and legs.

The distal end of a therapeutic catheter in accordance with the present invention may be inserted through a proximal orifice of the trocar. The therapeutic catheter may be urged forward through a lumen of the therapeutic catheter until a cutter of the therapeutic catheter contacts muscle tissue proximate the donor site. The mooring shaft may be urged forward within the lumen of the therapeutic catheter by applying a pushing force to the knob disposed at the proximal end of the mooring shaft. The mooring shaft may be urged forward until the mooring member of the therapeutic catheter contacts the muscle tissue of the donor site. The mooring member of the therapeutic catheter may be coupled to the muscle tissue of the donor site. In a preferred method, the mooring member is fixed to the muscle tissue by threading it into the tissue. In this preferred method, the mooring member may be rotated by applying a rotational force to the knob fixed to the proximal end of the mooring shaft.

A tendril of muscle tissue may be cut from the donor site. In a preferred method, the step of cutting the muscle tendril includes the step of urging a cutter into the muscle tissue of the donor site. The therapeutic catheter may be withdrawn from the donor site with the tendril of muscle tissue disposed within the cutter lumen.

Methods in accordance with the present invention have been envisioned in which a pulling force is applied to the knob disposed at the end of the mooring shaft. The step of pulling on the mooring shaft may be utilized to urge the muscle tendril proximally. Methods in accordance with the present invention have been envisioned in which one or more muscle tendrils are pulled into the lumen of the therapeutic catheter.

A guide catheter may be introduced into the vasculature of the patient. The guide catheter is urged forward until its distal tip is proximate a desired donee site. In a

preferred method, the distal tip is urged forward until it is disposed within the heart of the patient.

Once the distal end of the sheath is positioned proximate a desire donee site, the guide catheter may be advanced so that it's distal end contacts the tissue proximate the donee site. The moorings of the guide catheter may then be activated to stabilize the distal end of the guide catheter. In one embodiment of the present invention, each mooring comprises of a vacuum orifice in fluid communication with a vacuum lumen. In one method in accordance with the present invention, the moorings of the guide catheter are activated by applying vacuum from a vacuum source to the vacuum orifices via the vacuum lumens.

A pit or channel may be created in the tissue of the donee site proximate the distal end of the guide catheter. A number of methods are known in the art for creating channels or pits in body tissue. Examples of methods that may be suitable in some applications include mechanical cutting and burning by exposure to electromagnetic energy. Examples of types of electromagnetic energy that may be suitable in some applications include radio frequency energy and LASER light. A pit forming catheter may be utilized to remove material proximate the distal end of the guide catheter. A process in accordance with the present invention may include the step of inserting a pit forming catheter into the lumen of the guide catheter. The pit forming catheter may be urged forward until it's distal end is proximate the distal end of the guide catheter. A pit forming member disposed proximate the distal end of the pit forming catheter may be utilized to form a pit in the tissue proximate the donee site. Examples of pit forming members that may be suitable in some applications include knives, tomes, optical fibers,

and electrodes. The pit forming catheter may be withdrawn from the lumen of the guide catheter.

The distal end of a therapeutic catheter may be inserted into the proximal port of the guide catheter. The therapeutic catheter may be urged forward within the lumen of the guide catheter until the distal portion of the therapeutic catheter is disposed proximate the pit or channel in the tissue of the donee site. The muscle tendril may then be urged into the pit or channel in the tissue of the donee site. In a preferred method, the muscle tendril is urged forward by applying a pushing force on the knob fixed to the proximal end of the mooring shaft.

While the muscle tendril is disposed within the pit or channel in the tissue of the donee site, the muscle tendril may be, preferably, fixed in place with an anchor member. Various anchor members may be utilized without deviating from the spirit and scope of the present invention. Examples of anchor members include sutures, staples, cauterized areas of tissue, adhesive bonds, cork screws, wire loops, sleeves, barbs, and hooks. After the muscle tendril has been positioned in the pit or channel and preferably, anchored, the mooring member of the therapeutic catheter may be disengaged from the muscle tendril. In a preferred method, the mooring is disengaged from the muscle tendril by applying a rotational force to the knob fixed to the proximal end of the mooring shaft.

20

#### Brief Description of the Drawings

Figure 1 is a perspective view including a therapeutic catheter and a trocar in accordance with the present invention;



Figure 2 is a cross-sectional view of a trocar utilized to access a muscle within a donor site in a method in accordance with the present invention;

Figure 3 is a perspective view of the distal portion of a guide catheter in accordance with the present invention;

5        Figure 4 is a plan view of a patient and a therapeutic catheter system in accordance with the present invention;

Figure 5 is a plan view of an anchor member in accordance with an exemplary embodiment of the present invention;

Figure 6 is a cross-sectional view of the anchor member of Figure 5;

10       Figure 7 is a partial cross sectional view of the catheter of Figure 1;

Figure 8 is a partial cross sectional view of a distal portion of the catheter if Figure 7;

Figure 9 is a cross sectional view of a heart and a muscle tendril disposed within a heart wall of the heart;

15       Figure 10 is a partial cross section view of a catheter in accordance with an exemplary embodiment of the present invention;

Figure 11 is a plan view of a muscle tendril having a first end portion disposed within a first lumen of a first anchor and a second end portion disposed within a second lumen of a second anchor;

20       Figure 12 is a plan view of muscle tendril that is disposed within a heart which is shown in cross section;

Figure 13 is a plan view of an additional embodiment of an anchor in accordance with an exemplary embodiment of the present invention;

Figure 14 is a cross sectional view of a heart wall including a localized area of non-contracting tissue 652; and

Figure 15 is a partial cross sectional view of a heart and a muscle tendril spanning the chamber of a left ventricle of the heart.

5

#### Detailed Description of the Invention

The following detailed description should be read with reference to the drawings, in which like elements in different drawings are numbered identically. The drawings which are not necessarily to scale, depict selected embodiments and are not intended to  
10 limit the scope of the invention. Examples of constructions, materials, dimensions, and manufacturing processes are provided for various elements. Those skilled in the art will recognize that many of the examples provided have suitable alternatives which may be utilized.

Figure 1 is a perspective view of a therapeutic catheter 120 in accordance with the  
15 present invention. In the embodiment of Figure 1, therapeutic catheter 120 includes a distal end 124, a proximal end 122, and an elongate shaft 126 defining a lumen 130. A hub 128 is disposed about elongate shaft 126 proximate a proximal end 132 thereof. A cutter 136 is fixed to elongate shaft 126 proximate a distal end 134 thereof. Cutter 136 includes a distal edge 138 and a cutter lumen 140.

20 Therapeutic catheter 120 also includes a mooring member 146 disposed at a distal end of 144 of a mooring shaft 150. In the embodiment of Figure 1, mooring member 146 includes a helix 148. Mooring shaft 150 is slidably disposed within lumen 130 of elongate shaft 126 and cutter lumen 140 of cutter 136. A knob 160 is fixed to a proximal

end 146 of mooring shaft 150. In a preferred embodiment, knob 160 is adapted to be rotated by the fingers of a physician. In this preferred embodiment, the rotary motion of knob 160 is transferred to mooring member 146 via mooring shaft 150.

In a preferred embodiment, mooring member 146 and mooring shaft 150 are  
5 comprised of a metallic wire. Metals that may be suitable in some applications include stainless steel and nickel titanium alloy. It is to be appreciated that other metallic and non-metallic materials may be utilized without deviating from the spirit and scope of the present invention.

It will also be appreciated that elongate shaft 126 may be comprised of many  
10 materials without deviating from the spirit and scope of the present invention. In a preferred embodiment, elongate shaft 126 is comprised of polyether block amide (PEBA). Polyether block amide is commercially available from Atochem Polymers of Birdsboro, Pennsylvania under the trade name PEBAX. Also in a preferred embodiment, elongate shaft 126 is fabricated using an extrusion process.

15 It is to be understood that other manufacturing processes can be used without departing from the spirit and scope of the present invention. Elongate shaft 126 may also be comprised of other materials without departing from the spirit of scope of this invention. Examples of materials that may be suitable in some applications include: polyethylene (PE), polypropylene (PP), polyvinylchloride (PVC), polyurethane, and  
20 polytetrafluoroethylene (PTFE). Elongate shaft 126 may also include a reinforcement member. Examples of reinforcement members that may be suitable in some applications include a plurality of strands disposed in a braided pattern, a plurality of fibers knitted together, and a coiled wire.

Therapeutic catheter 120 may include one or more radiopaque markers. One example of a radiopaque marker is a band of radiopaque material disposed proximate the distal end of therapeutic catheter 120. Radiopaque bands of this type aid the physician in determining the location of the distal end of the device relative to the patient's anatomy.

5 The radiopaque band may be comprised of a number of materials. Examples of materials that may be suitable in some applications include gold, platinum, tungsten, iron, silver, and thermoplastic material loaded with a radiopaque filler. Examples of radiopaque filler that may be suitable in some applications include barium sulfate, bismuth subcarbonate, bismuth trioxide, bismuth oxychloride, bismuth subcarbonate, tungsten powder, and

10 depleted uranium.

Cutter 136 of therapeutic catheter 120 may be comprised of a variety of metallic and non-metallic materials. Examples of metallic materials that may be suitable in some applications include stainless steel, and nickel-titanium alloy. Examples of non-metallic materials that may be suitable in some applications include polycarbonate, polyacrylate,

15 polyimide, and polyamide. Cutter 136 may be fixed to elongate shaft 126 using any suitable method. Examples of methods that may be suitable in some applications include welding, adhesive bonding, and mechanical coupling.

Figure 2 is a cross-sectional view of a trocar 256 disposed proximate a donor site 270. Trocar 256 includes a body 258 defining a trocar lumen 262. Body 258 includes a

20 flange 264, a penetrating portion 266, a distal end 254, and a proximal end 252. In Figure 2, penetrating portion 266 of body 258 of trocar 256 has penetrated a skin 268 of a human body proximate donor site 270. As shown in Figure 2, a distal end 254 of trocar 256 is disposed proximate a muscle 272 of donor site 270. A proximal aperture 274 of

trocar 256 is in fluid communication with trocar lumen 262. In a preferred embodiment, trocar lumen 262 of trocar 256 is adapted to receive therapeutic catheter 120. In a preferred method in accordance with the present invention, distal end 124 of therapeutic catheter 120 is inserted into trocar lumen 262 through proximal aperture 274.

5        Figure 3 is a perspective view of a distal portion 156 of a guide catheter 158 in accordance with the present invention. Guide catheter 158 includes an elongate tubular member 166 defining a central lumen 160. A plurality of moorings 168 are disposed proximate a distal end 164 of guide catheter 158. In one method in accordance with the present invention, moorings 168 may be utilized to retain distal end 164 of guide catheter  
10    158 proximate a donee site. In the embodiment of Figure 3, each mooring 168 comprises a vacuum orifice 172. Each vacuum orifice 172 is in fluid communication with a vacuum lumen 170 defined by elongate tubular member 166.

Other embodiments of moorings 168 are possible without deviating from the spirit or scope of the present invention. For example, each mooring 168 may be  
15    comprised of an elongate wire with a helix disposed proximate its distal end. The helical end of the elongate wire may be "threaded" into the tissue proximate the donee site by rotating the wire. Additional examples, of moorings 168 that may be appropriate in some applications include hooks and barbs.

Guide catheter 158 may be comprised of many materials without deviating from  
20    the spirit and scope of the present invention. In a preferred embodiment, guide catheter 158 is comprised of polyether block amide (PEBA). Polyether block amide is commercially available from Atochem Polymers of Birdsboro, Pennsylvania under the

trade name PEBAX. Also in a preferred embodiment, guide catheter 158 is fabricated using an extrusion process.

It is to be understood that other manufacturing processes can be used without departing from the spirit and scope of the present invention. Guide catheter 158 may also  
5 be comprised of other materials without departing from the spirit of scope of this invention. Examples of materials that may be suitable in some applications include: polyethylene (PE), polypropylene (PP), polyvinylchloride (PVC), polyurethane, and polytetrafluoroethylene (PTFE). Guide catheter 158 may also include a reinforcement member. Examples of reinforcement members that may be suitable in some applications  
10 include a plurality of strands disposed in a braided pattern, a plurality of fibers knitted together, and a coiled wire.

Guide catheter 158 may include one or more radiopaque markers. One example of a radiopaque marker is a band of radiopaque material disposed proximate the distal end of guide catheter 158. Radiopaque bands of this type aid the physician in  
15 determining the location of the distal end of the device relative to the patient's anatomy. The radiopaque band may be comprised of a number of materials. Examples of materials that may be suitable in some applications include gold, platinum, tungsten, iron, silver, and thermoplastic material loaded with a radiopaque filler. Examples of radiopaque filler that may be suitable in some applications include barium sulfate, bismuth subcarbonate,  
20 bismuth trioxide, bismuth oxychloride, bismuth subcarbonate, tungsten powder, and depleted uranium.

Figure 4 is a plan view of a patient 202 and a therapeutic catheter system 200 including a guide catheter 158 having a central lumen and a plurality of moorings 168

disposed proximate the distal end thereof. In the embodiment of Figure 4, each mooring 168 comprises a vacuum orifice 172 in fluid communication with a vacuum lumen 170 defined by guide catheter 158. A multi-port adapter 174 is disposed at a proximal end 162 of guide catheter 158. A vacuum port 176 of multi-port adapter 174 is in fluid  
5 communication with vacuum lumens 170 of guide catheter 158.

An actuator 178 is coupled to moorings 168 of guide catheter 158. In the embodiment of Figure 4, actuator 178 includes an actuating lever 180 and a valve body 184. Valve body 184 is in fluid communication with vacuum orifices 172 via vacuum port 176 of multi-port adapter 174 and vacuum lumens 170 of guide catheter 158. Valve  
10 body 184 is also in fluid communication with a vacuum source 186. In the embodiment of Figure 4, actuator 178 may selectively actuate moorings 168 by selectively placing vacuum orifices 172 in fluid communication with vacuum source 186.

A therapeutic catheter 120 is slidably disposed within central lumen 160 of guide catheter 158 and passes through a proximal port 188 of multi-port adapter 174. In the  
15 embodiment of Figure 4, therapeutic catheter 120 includes an elongate shaft 126 defining a lumen 130 (not shown). A hub 128 is disposed about elongate shaft 126 proximate a proximal end 132 thereof. A cutter 136 (not shown) is fixed to elongate shaft 126 proximate a distal end 134 thereof.

A mooring shaft 150 is slidably disposed within the lumen of elongate shaft 126.  
20 A mooring member is disposed at the distal end of mooring shaft 150. A knob 160 is fixed to a proximal end 142 of mooring shaft 150. In a preferred embodiment, knob 160 is adapted to be rotated by the fingers of a physician. In this preferred embodiment, the

rotary motion of knob 160 is transferred to the mooring member disposed at the distal end of mooring shaft 150.

An access catheter 204 is positioned such that its distal end is positioned within a blood vessel 206 of a vasculature 208 of patient 202. Access catheter 204 may aid in the  
5 introduction of guide catheter 158 into blood vessel 206.

In Figure 4, distal end 164 of guide catheter 158 is positioned within a heart muscle 172 of patient 202. Distal end 164 of guide catheter 158 is fixed to heart muscle 172 by moorings 168.

Having thus described Figure 1 through Figure 4, methods in accordance with the  
10 present invention may now be described with reference thereto. It should be understood that steps may be omitted from these processes and/or the order of the steps may be changed without deviating from the spirit or scope of the invention. It is anticipated that in some applications, two or more steps may be performed more or less simultaneously to promote efficiency.

15 A method in accordance with the present invention may include the step of penetrating the skin of a patient with a trocar near a donor site. In a preferred method, the donor site includes muscle tissue. Examples of donor sites that may be suitable in some applications include arms and legs.

The distal end of a therapeutic catheter in accordance with the present invention  
20 may be inserted through a proximal orifice of the trocar. The therapeutic catheter may be urged forward through a lumen of the therapeutic catheter until a cutter of the therapeutic catheter contacts muscle tissue proximate the donor site. The mooring shaft may be urged forward within the lumen of the therapeutic catheter by applying a pushing force to



the knob disposed at the proximal end of the mooring shaft. The mooring shaft may be urged forward until the mooring member of the therapeutic catheter contacts the muscle tissue of the donor site. The mooring member of the therapeutic catheter may be coupled to the muscle tissue of the donor site. In a preferred method, the mooring member is  
5 fixed to the muscle tissue by threading it into the tissue. In this preferred method, the mooring member may be rotated by applying a rotational force to the knob fixed to the proximal end of the mooring shaft.

A tendril of muscle tissue may be cut from the donor site. In a preferred method, the step of cutting the muscle tendril includes the step of urging a cutter into the muscle  
10 tissue of the donor site. The therapeutic catheter may be withdrawn from the donor site with the tendril of muscle tissue disposed within the cutter lumen.

Methods in accordance with the present invention have been envisioned in which a pulling force is applied to the knob disposed at the end of the mooring shaft. The step of pulling on the mooring shaft may be utilized to urge the muscle tendril proximally.  
15 Methods in accordance with the present invention have been envisioned in which one or more muscle tendrils are pulled into the lumen of the therapeutic catheter.

A guide catheter may be introduced into the vasculature of the patient. The guide catheter is urged forward until it's distal tip is proximate a desired donee site. In a preferred method, the distal tip is urged forward until it is disposed within the heart of the  
20 patient.

Once the distal end of the sheath is positioned proximate a desired donee site, the guide catheter may be advanced so that it's distal end contacts the tissue proximate the donee site. The moorings of the guide catheter may then be activated to stabilize the

distal end of the guide catheter. In one embodiment of the present invention, each mooring comprises of a vacuum orifice in fluid communication with a vacuum lumen. In one method in accordance with the present invention, the moorings of the guide catheter are activated by applying vacuum from a vacuum source to the vacuum orifices via the vacuum lumens.

A pit or channel may be created in the tissue of the donee site proximate the distal end of the guide catheter. A number of methods may be utilized to create channels or pits in the tissue. Examples of methods that may be suitable in some applications include mechanical cutting and burning by exposure to electromagnetic energy. Examples of general types of electromagnetic energy that may be suitable in some applications include radio frequency energy and LASER light. A pit forming catheter may be utilized to remove material proximate the distal end of the guide catheter. A process in accordance with the present invention may include the step of inserting a pit forming catheter into the lumen of the guide catheter. The pit forming catheter may be urged forward until its distal end is proximate the distal end of the guide catheter. A pit forming member disposed proximate the distal end of the pit forming catheter may be utilized to form a pit in the tissue proximate the donee site. Examples of pit forming members that may be suitable in some applications include knives, tomes, optical fibers, and electrodes. The pit forming catheter may be withdrawn from the lumen of the guide catheter.

The distal end of a therapeutic catheter may be inserted into the proximal port of the guide catheter. The therapeutic catheter may be urged forward within the lumen of the guide catheter until the distal portion of the therapeutic catheter is disposed proximate the pit or channel in the tissue of the donee site. The muscle tendril may then be urged

into the pit or channel in the tissue of the donee site. In a preferred method, the muscle tendril is urged forward by applying a pushing force on the knob fixed to the proximal end of the mooring shaft.

While the muscle tendril is disposed within the pit or channel in the tissue of the donee site, the muscle tendril may be, preferably, fixed in place with an anchor member. Various anchor members may be utilized without deviating from the spirit and scope of the present invention. Examples of anchor members include sutures, staples, cauterized areas of tissue, adhesive bonds, cork screws, wire loops, sleeves, barbs, and hooks. After the muscle tendril has been positioned in the pit or channel and preferably, anchored, the mooring member of the therapeutic catheter may be disengaged from the muscle tendril. In a preferred method, the mooring is disengaged from the muscle tendril by applying a rotational force to the knob fixed to the proximal end of the mooring shaft.

Figure 5 is a plan view of an anchor member 300 in accordance with the present invention. Anchor member 300 comprises a generally tubular frame 306 defining a lumen 308. Anchor member 300 also includes a plurality of inwardly direct barbs 302 that are directed into lumen 308, and a plurality of outwardly direct barbs 304 that are directed away from lumen 308.

Figure 6 is a cross-sectional view of anchor member 300 of Figure 5. In Figure 6, it may be appreciated that anchor member 300 includes a point 320. In one method in accordance with the present invention, point 320 of anchor member 300 may be urged into the tissue of a donee site. In a particularly preferred embodiment, point 320 of anchor member 300 may be urged into the tissue of a donee site without the prior step of creating a pit or channel in the tissue. In Figure 6, inwardly direct barbs 302 can be seen

protruding into lumen 308 of anchor member 300. In a method in accordance with the present invention, an end portion a muscle tendril may be inserted into lumen 308, and inwardly direct barbs 302 may assist in retaining the end portion of the muscle tendril within lumen 308.

5        Figure 7 is a partial cross sectional view of catheter 120 of Figure 1. In the embodiment of Figure 7, a muscle tendril 322 is partially disposed within cutter lumen 140 of cutter 136. A first end portion 324A of muscle tendril 322 is disposed within lumen 308 of anchor member 300. Figure 8 is a partial cross sectional view of a distal portion of catheter 120. In the embodiment of Figure 8, muscle tendril 322 and anchor  
10    member 300 have been urged into a donee tissue 326.

Figure 9 is a cross sectional view of a heart 428 and a muscle tendril 422 disposed within a heart wall 430 of heart 428. Heart wall 430 has an outer surface 432 and an inner surface 434. In a useful embodiment, muscle tendril 422 is disposed between inner surface 434 and outer surface 432. In a preferred embodiment, muscle tendril 422  
15    disposed so that the longitudinal axis of muscle tendril 422 is generally concentric with outer surface 432 of heart 428. In a particularly preferred embodiment, muscle tendril 422 disposed so that the longitudinal axis of muscle tendril 422 is generally concentric with outer surface 432 and inner surface 434 of heart 428. In Figure 9 it may be appreciated that muscle tendril 422 has a radius of curvature. In a particularly preferred  
20    embodiment, the radius of curvature of muscle tendril 422 is similar to the radius of curvature of heart wall 430. In a particularly preferred embodiment, the radius of curvature of muscle tendril 422 falls between an inner radius 442 of heart wall 430 and an outer radius 444 of heart wall 430.

Figure 10 is a partial cross section view of a catheter 446 in accordance with an exemplary embodiment of the present invention. Catheter 446 includes a cutter 436 defining a cutter lumen 440. Cutter 436 is has a generally curved shape with a radius R. A muscle tendril 422 is partially disposed within cutter lumen 440. The curved shape of catheter 446 may facilitate insertion of muscle tendril 422 into heart wall 430 of heart 428, as shown in Figure 9. In a particularly preferred embodiment, the radius of curvature of cutter 436 is similar to the radius of curvature of heart wall 430. In a particularly preferred embodiment, the radius of curvature of catheter 446 falls between inner radius 442 of heart wall 430 and outer radius 444 of heart wall 430. Although one muscle tendril is shown in Figure 9, it is to be appreciated that a plurality of muscle tendril may be, preferably, inserted into heart wall 430 of heart 428.

Figure 11 is a plan view of a muscle tendril 522 having a first end portion 524A and a second end portion 524B. In the embodiment of Figure 11, first end portion 524A of muscle tendril 522 is disposed within a first lumen 508A of a first anchor 550A and second end portion 524B of muscle tendril 522 is disposed within a second lumen 508B of a second anchor 550B.

Figure 12 is a plan view of muscle tendril 522 of Figure 11. In Figure 12, muscle tendril 522 is disposed within a heart 528 which is shown in cross section. Heart 528 includes a left ventricle 20, a right ventricle 22, a left atrium 24, and a right atrium 26. In a preferred embodiment, muscle tendril 522 aids the life sustaining blood pumping action of heart 528. During this blood pumping action, blood from the upper portion of the body flows into right atrium 26 via the superior vena cava 28. Blood from the lower portion of the body flows into the right atrium 26 via the inferior vena cava 30. A

tricuspid valve 32 is in fluid communication with both the right atrium 26 and the right ventricle 22. When tricuspid valve 32 opens, it allows blood to flow from right atrium 26 into right ventricle 22. During each heart beat, tricuspid valve 32 closes and right ventricle 22 contracts, pumping blood through the pulmonary valve 34 into the pulmonary artery 36. The pulmonary artery carries blood to the lungs of the patient.

After becoming oxygenated in the lungs, blood returns to the heart via a plurality of pulmonary veins 38 which are each in fluid communication with the left atrium 24. A mitral valve 40 is in fluid communication with both left atrium 24 and left ventricle 20. Blood returning from the lungs via pulmonary veins 38 may pass through mitral valve 40 into left ventricle 20. During each heart beat, mitral valve 40 closes and left ventricle 20 contracts, pumping blood through an aortic valve 42 and into the aorta 44. After passing through the aorta 44, oxygenated blood is distributed throughout the body of the patient.

The walls of a diseased heart may include areas of non-contracting tissue that may interfere with the life sustaining blood pumping action of heart 528. An area of non-contracting tissue may comprise a myocardial infarction, a stenosis, and etc. Areas of non-contracting tissue may be caused by, for example, ischemia, which is a decreased supply of blood to an area of tissue. Non-contracting tissue may also be the result of idiopathic disease, which is a disease which develops without an apparent or known cause. Additionally, an area of non-contracting tissue may comprise an area of necrosis which is localized tissue death. An area of non-contracting tissue may also comprise tissue which is hibernating due to reduced blood flow to the effected tissue.

As shown in Figure 12, heart 528 includes a middle heart wall 46 that is disposed between the left ventricle 20 and the right ventricle 22. Left ventricle 20 includes a left

heart wall 48, a dorsal heart wall 50, and a ventral heart wall 52 (not shown). Left ventricle 20 also includes a chamber 54 defined by middle heart wall 46, left heart wall 48, dorsal heart wall 50, and ventral heart wall 52. Right ventricle 22 includes a right heart wall 56, a dorsal heart wall 58, and a ventral heart wall 60 (not shown). Right  
5 ventricle 22 also includes a chamber 62 defined by middle heart wall 46, right heart wall 56, dorsal heart wall 50, and ventral heart wall 60.

In the embodiment of Figure 12, first anchor 550A and first end portion 524A of muscle tendril 522 are disposed within left heart wall 48 of left ventricle 20. In a similar fashion, second anchor 550B and second end portion 524B of muscle tendril 522 are  
10 disposed within right heart wall 56 of right ventricle 22. Also in the embodiment of Figure 12, muscle tendril 522 passes through middle heart wall 46 of heart 528. In a preferred embodiment, muscle tendril 522 assists heart 528 in pumping blood. In a particularly preferred embodiment, muscle tendril 522 assists heart 528 in pumping blood by contracting when left ventricle 20 and right ventricle 22 of heart 528 contract (i.e.,  
15 muscle tendril itself contracts).

Figure 13 is a plan view of an additional embodiment of an anchor 654 in accordance with the present invention. A distal end 656 of an elongate member 658 is releasably fixed to anchor 654. In the embodiment of Figure 13, the releasable fixing of elongate member 658 to anchor 654 is accomplished utilizing a sacrificial material 660  
20 disposed between distal end 656 of elongate member 658 and anchor 654. In a preferred embodiment, sacrificial material 660 comprises a material that may be selectively decayed via electrolytic corrosion. For example, when it is desirable to disconnect elongate member 658 from anchor 654, an electrical current may be passed through

sacrificial material 660. This electrical current may cause sacrificial material 660 to corrode, dissolve, or disintegrate until the bond between elongate member 658 and anchor 654 is broken.

Figure 14 is a cross sectional view of a heart wall 630 of a heart 628 including a localized area of non-contracting tissue 652. Non-contracting tissue 652 may comprise a myocardial infarction, an ischemia, a stenosis, an area of necrosis, hibernating tissue, etc. An insertion catheter 662 is also illustrated in Figure 14. In a method in accordance with the present invention, insertion catheter 662 may be utilized to treat heart wall 630. In Figure 14, insertion catheter 662 includes a sheath 664 defining a lumen 666. A first elongate member 658A and a second elongate member 658B are both partially disposed within lumen 666 of sheath 664. First elongate member 658A has a distal end that is releasably fixed to a first anchor 654A. In a similar fashion, second elongate member 658B has a distal end that is releasably fixed to a second anchor 654B. As shown in Figure 14, a first end portion 624A of a muscle tendril 622 is fixed to first anchor 654A, and a second end portion 624B of a muscle tendril 622 is fixed to second anchor 654B. First anchor 654A is disposed within heart wall 630 proximate a first side 668 of non-contracting tissue 652. Second anchor 654B is disposed within heart wall 630 proximate a second side 670 of non-contracting tissue 652. In a preferred embodiment, muscle tendril 622 assists heart 628 in pumping blood. In a particularly preferred embodiment, muscle tendril 622 assists heart 628 in pumping blood by contracting when heart wall 630 contracts.

Figure 15 is a partial cross sectional view of a heart 628. In the embodiment of Figure 15, a distal portion of insertion catheter 662 has been advanced through an aorta



44 and a mitral valve 40 of heart 628. A muscle tendril 622 is disposed within a left ventricle 20 of heart 628. A first end portion 672 of muscle tendril 622 is fixed to a first heart wall 630A and a second end portion 674 of muscle tendril 622 is fixed to a second heart wall 630B.

5           In the embodiment of Figure 15, muscle tendril 622 is disposed so that it spans a chamber of left ventricle 20. Embodiments of the present invention have been envisioned in which muscle tendrils span other chambers of the heart. Examples of heart chambers include the left atrium chamber, the right atrium chamber, and the right ventricle chamber. Muscle tendrils disposed in this manner may aid the blood pumping action of  
10 the heart chambers. Embodiments of the present invention have also been envisioned in which a plurality of muscle tendrils span one or more chambers of the heart.

          The aforementioned embodiments of the present inventions describe muscle fibril implantations which may be caused to contract by developing electrical connections to adjacent conducting myocytes. It is also contemplated that an external electrical  
15 stimulator could be utilized to synchronously excite the muscle fibrils in a manner as to maximize the beating efficiency of the heart. A series of electrically excitable anchors is envisioned that could be connected to a muscle stimulator, similar to those devices used in cardiac myoplasty procedures.

          Having thus described the preferred embodiments of the present invention, those  
20 of skill in the art will readily appreciate that yet other embodiments may be made and used within the scope of the claims hereto attached. Numerous advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative.

Changes may be made in details, particularly in matters of shape, size, and arrangement of parts without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A method of increasing the volume of blood pumped by a heart muscle, comprising the steps of:

providing a guide catheter comprising an elongate shaft having a proximal end, a distal end, and a lumen extending through at least a portion thereof;

providing a therapeutic catheter comprising an elongate shaft having a proximal end, a distal end, and a lumen extending through at least a portion thereof;

the therapeutic catheter further including a cutter having a cutter lumen fixed to the distal end of the elongate shaft;

providing an anchor shaft slidably disposed within the lumen of the elongate shaft;

the anchor shaft having an anchor member disposed proximate a distal end thereof;

engaging a muscle of a donor site with the anchor member of the anchor shaft;

penetrating the muscle of the donor site with the cutter to form a muscle tendril;

withdrawing the muscle tendril from the muscle of the donor site;

positioning the distal end of the guide catheter proximate a donee site;

inserting the therapeutic catheter into the lumen of the guide catheter;

advancing the therapeutic catheter distally through the lumen of the guide catheter;

inserting the muscle tendril into the tissue of the donee site; and

disengaging the anchor member of the anchor shaft from the muscle tendril.

2. The method of claim 1, wherein the step of inserting the muscle tendril into the tissue of the donee site includes the step of applying a pushing force to the anchor shaft.

3. The method of claim 1, wherein the step of disengaging the anchor member of the anchor shaft from the muscle tendril includes the step of rotating the anchor shaft.

4. The method of claim 1, wherein the anchor member of the anchor shaft is comprised of a helix.

5. The method of claim 1, wherein the guide catheter includes at least one anchor disposed proximate the distal end thereof.

6. The method of claim 1, further including the step fixing the distal end of the guide catheter to a tissue proximate the donee site.

7. The method of claim 1, further including the step fixing the distal end of the guide catheter to a tissue proximate the donee site; and

the step fixing the distal end of the guide catheter to a tissue proximate the donee site includes the step of activating an anchor of the guide catheter.

8. A method of increasing the volume of blood pumped by a heart muscle, comprising the steps of:
- providing a guide catheter comprising an elongate shaft having a proximal end, a distal end, and a lumen extending through at least a portion thereof;
  - the guide catheter including at least one anchor disposed proximate the distal end thereof;
  - providing a therapeutic catheter comprising an elongate shaft having a proximal end, a distal end, and a lumen extending through at least a portion thereof;
  - the therapeutic catheter further including a cutter having a cutter lumen fixed to the distal end of the elongate shaft;
  - providing an anchor shaft slidably disposed within the lumen of the elongate shaft;
  - the anchor shaft having an anchor member disposed proximate a distal end thereof;
  - engaging a muscle of a donor site with the anchor member of the anchor shaft;
  - penetrating the muscle of the donor site with the cutter to form a muscle tendril;
  - withdrawing the muscle tendril from the muscle of the donor site;
  - positioning the distal end of the guide catheter proximate a donee site;
  - activating the at least one anchor of the guide catheter;
  - wherein the distal end of the guide catheter is selectively fixed to a tissue proximate the donee site;
  - inserting the therapeutic catheter into the lumen of the guide catheter;

advancing the therapeutic catheter distally through the lumen of the guide catheter;

inserting the muscle tendril into the tissue of the donee site; and

disengaging the anchor member of the anchor shaft from the muscle tendril.

9. The method of claim 8, wherein the step of inserting the muscle tendril into the tissue of the donee site includes the step of applying a pushing force to the anchor shaft.

10. The method of claim 8, wherein the step of disengaging the anchor member of the anchor shaft from the muscle tendril includes the step of rotating the anchor shaft.

11. The method of claim 8, wherein the anchor member of the anchor shaft is comprised of a helix.

12. The method of claim 8, wherein the at least one anchor of the guide catheter comprises a vacuum orifice.

13. The method of claim 8, wherein the at least one anchor of the guide catheter comprises a vacuum orifice and the step of activating the at least one anchor of the guide catheter includes the step of placing the vacuum orifice in fluid communication with a vacuum source.

14. A method of increasing the volume of blood pumped by a heart muscle, comprising the steps of:

providing a guide catheter comprising an elongate shaft having a proximal end, a distal end, and a lumen extending through at least a portion thereof;

the guide catheter including at least one anchor disposed proximate the distal end thereof;

providing a therapeutic catheter comprising an elongate shaft having a proximal end, a distal end, and a lumen extending through at least a portion thereof;

the therapeutic catheter further including a cutter having a cutter lumen fixed to the distal end of the elongate shaft;

providing an anchor shaft slidably disposed within the lumen of the elongate shaft;

the anchor shaft having an anchor member disposed proximate a distal end thereof;

providing a trocar having a lumen;

penetrating a skin of a patient with the trocar proximate a donor site;

inserting the therapeutic catheter into the lumen of the trocar;

engaging a muscle of the donor site with the anchor member of the anchor shaft;

penetrating the muscle of the donor site with the cutter;

wherein a muscle tendril is disposed within the lumen of the cutter;

withdrawing the muscle tendril from the muscle of the donee site;

inserting the distal end of the guide catheter into a lumen of a blood vessel of a vasculature of the patient;

advancing the guide catheter through the vasculature of the patient;  
positioning the distal end of the guide catheter proximate a donee site;  
activating the at least one anchor of the guide catheter;  
wherein the distal end of the guide catheter is selectively fixed to a tissue proximate the donee site;  
removing material from a tissue of the donee site proximate the distal end of the guide catheter to create a pit defined by the tissue of the donee site;  
inserting the therapeutic catheter into the lumen of the guide catheter;  
advancing the therapeutic catheter distally through the lumen of the guide catheter;  
positioning the distal end of the therapeutic catheter proximate the tissue of the donee site;  
inserting the muscle tendril into the tissue of the donee site; and  
disengaging the anchor member of the anchor shaft from the muscle tendril.

15. The method of claim 14, wherein the step of inserting the muscle tendril into the tissue of the donee site includes the step of applying a pushing force to the anchor shaft.

16. The method of claim 14, wherein the step of disengaging the anchor member of the anchor shaft from the muscle tendril includes the step of rotating the anchor shaft.



17. The method of claim 14, wherein the anchor member of the anchor shaft is comprised of a helix.

18. The method of claim 14, wherein the at least one anchor of the guide catheter comprises a vacuum orifice.

19. The method of claim 14, wherein the at least one anchor of the guide catheter comprises a vacuum orifice and the step of activating the at least one anchor of the guide catheter includes the step of placing the vacuum orifice in fluid communication with a vacuum source.

20. A method of treating a heart wall having an area of non-contracting tissue, comprising the steps of:

locating the non-contracting tissue;

fixing a first end of a muscle tendril to the heart wall proximate a first end of the non-contracting tissue; and

fixing a second end of a muscle tendril proximate a second end of the non-contracting tissue.

21. A method of increasing the volume of blood pumped by a heart, comprising the steps of:

providing a muscle tendril having a first end, a second end, and an intermediate portion therebetween;

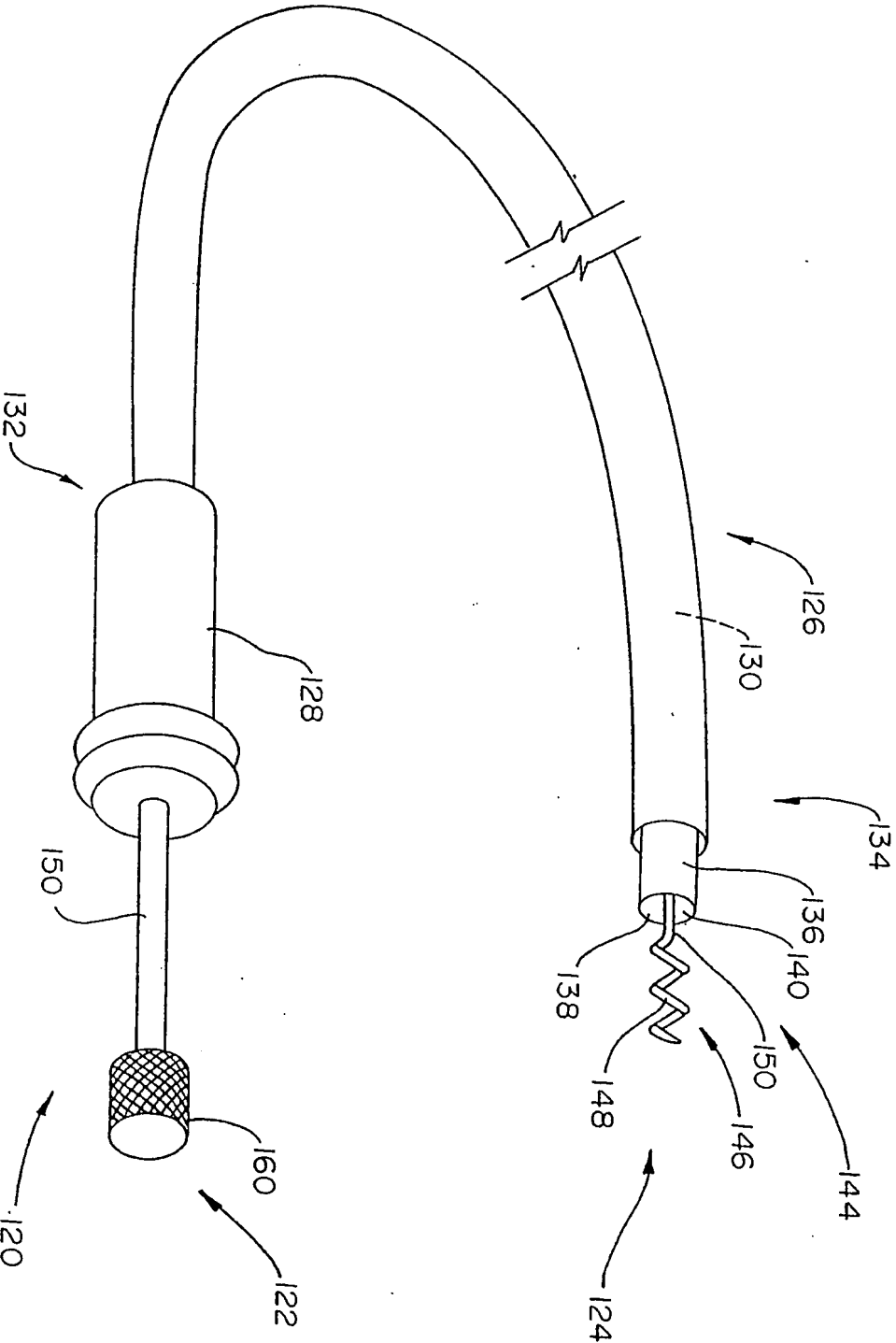
positioning the muscle tendril within a chamber of the heart;  
fixing the first end of the muscle tendril to a first wall of the heart;  
fixing the second end of the muscle fiber to a second wall of the heart; and  
wherein an intermediate portion of the muscle fibril bridges the chamber of the heart.

22. The method of claim 21, wherein the chamber of the heart is a left ventricle.

23. The method of claim 21, wherein the chamber of the heart is a right ventricle.

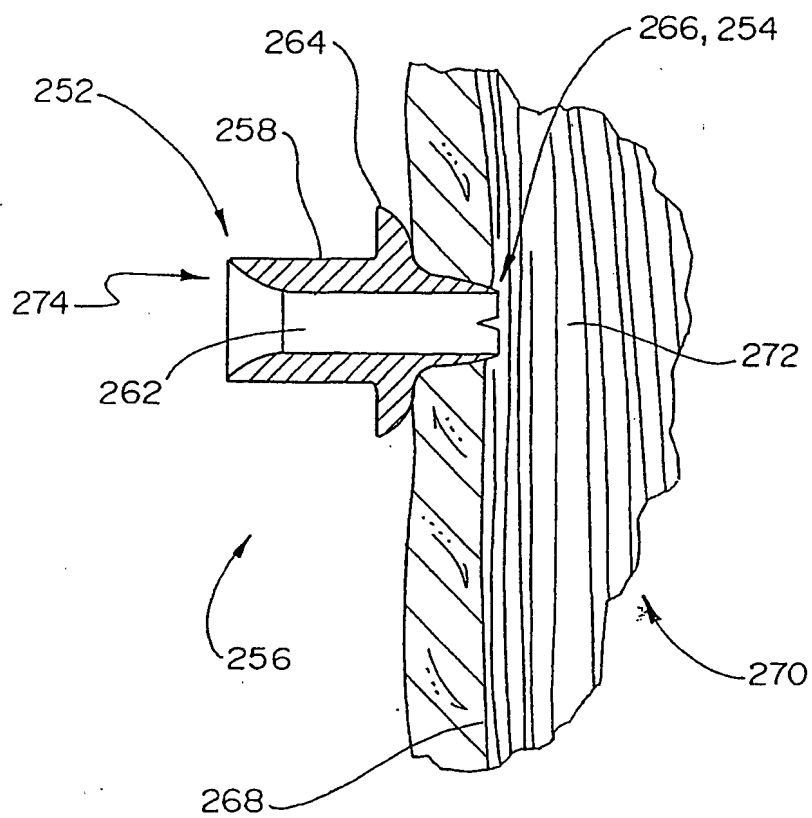
24. The method of claim 21, wherein the chamber of the heart is a left atrium.

25. The method of claim 21, wherein the chamber of the heart is a right atrium.

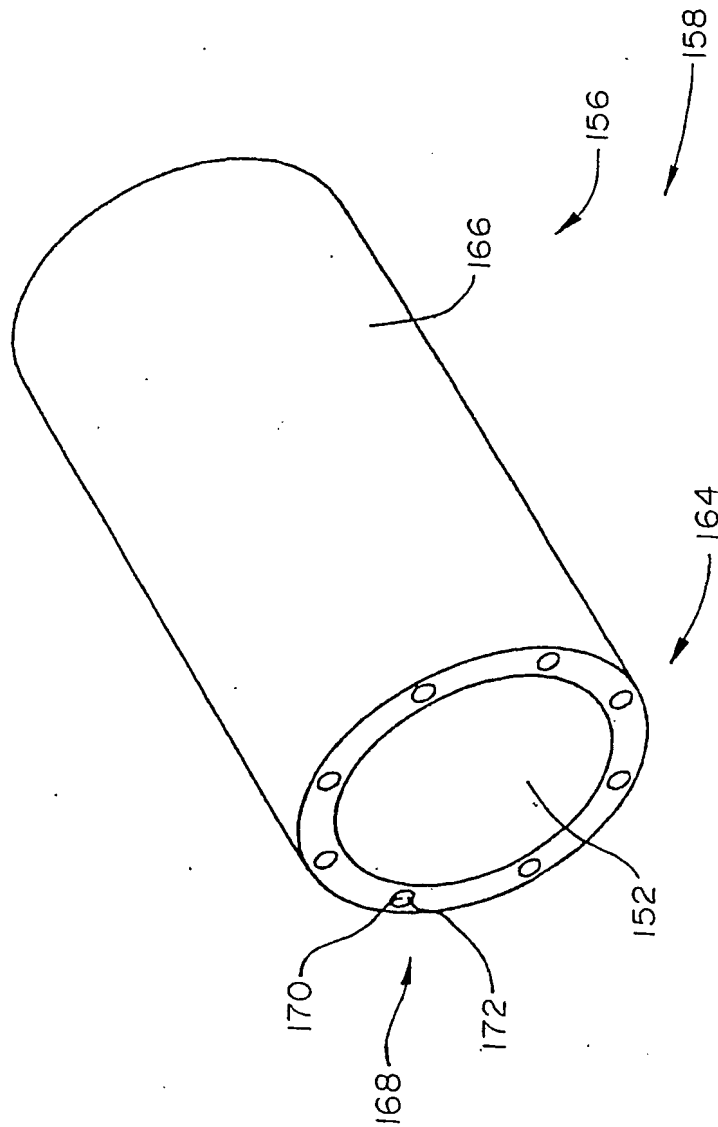


*Fig. 1*

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*Fig. 2*

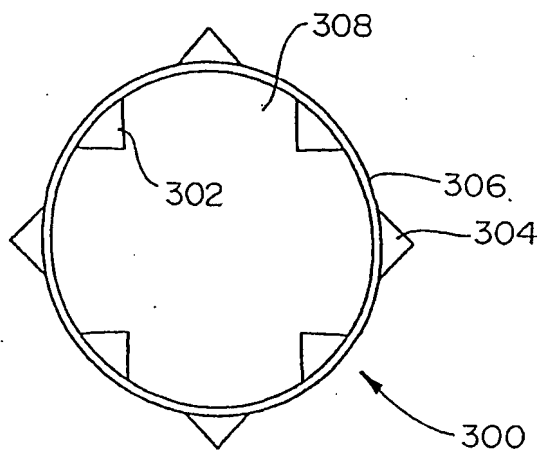
*Fig. 3*



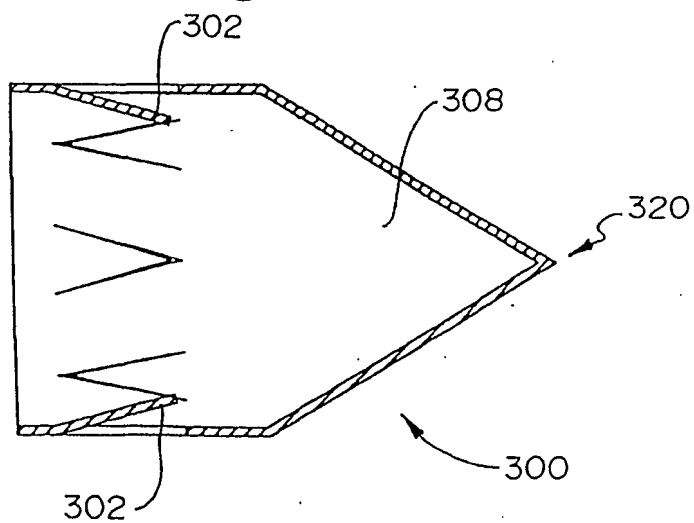


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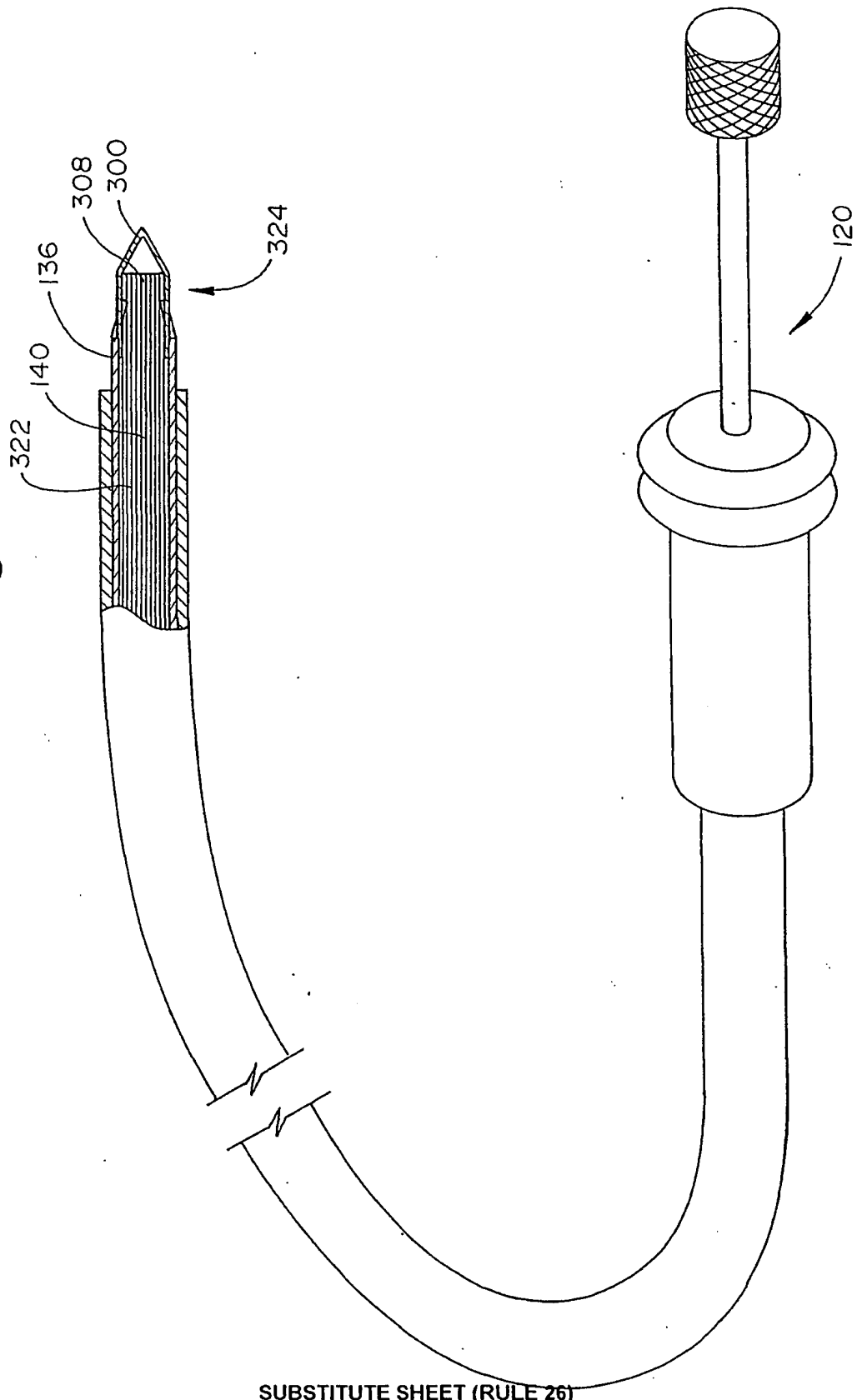
*Fig. 5*



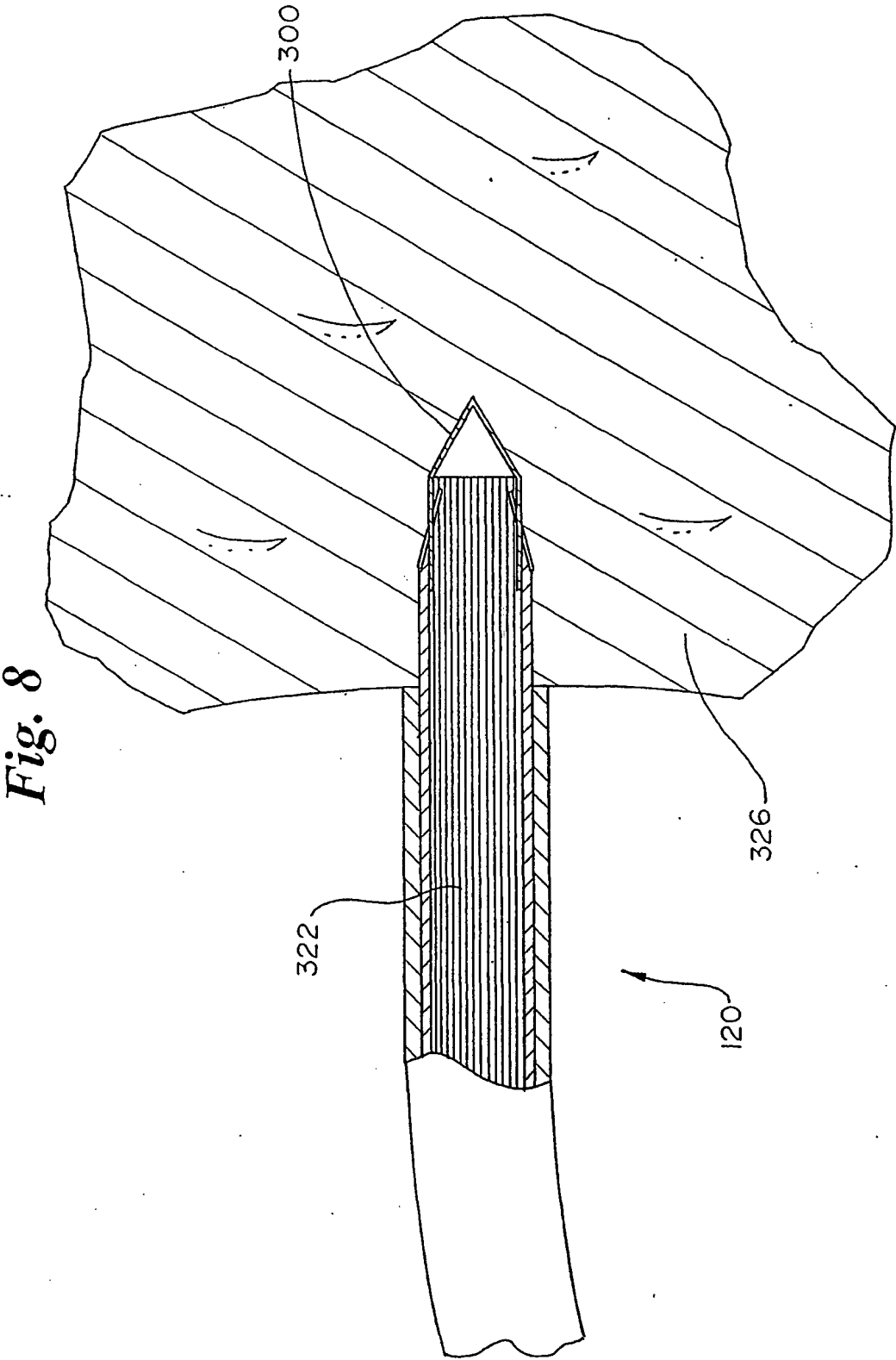
*Fig. 6*



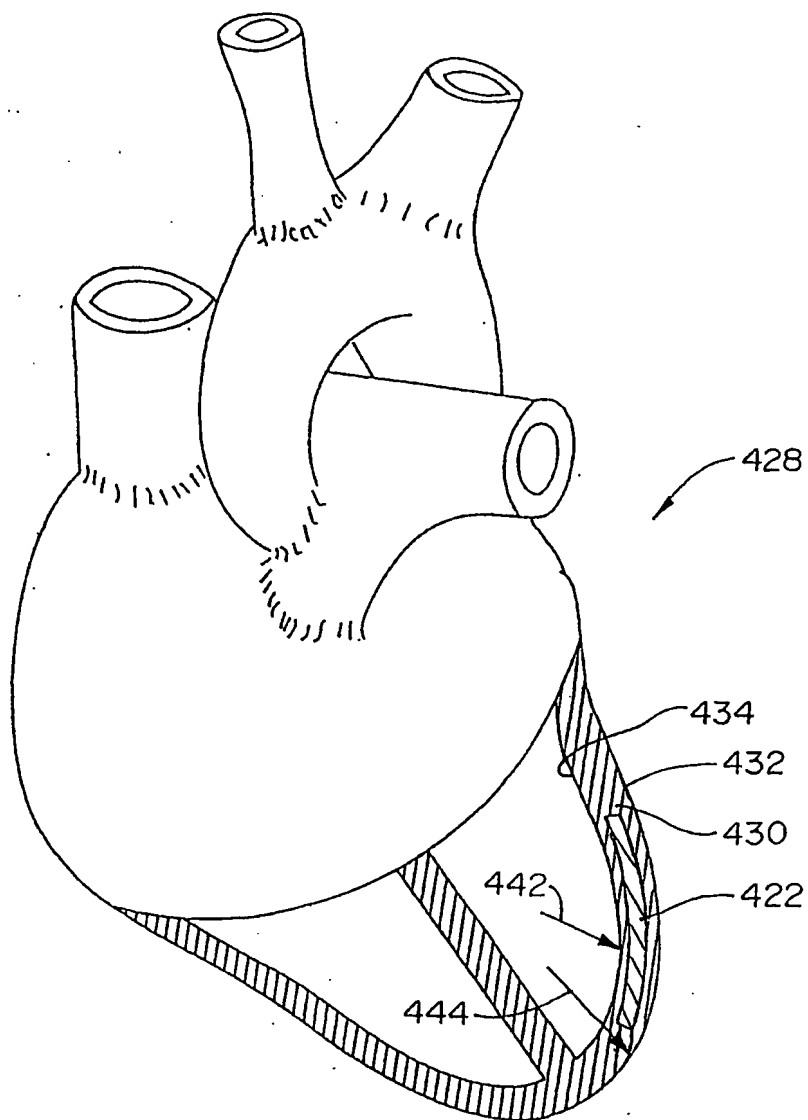
**Fig. 7**





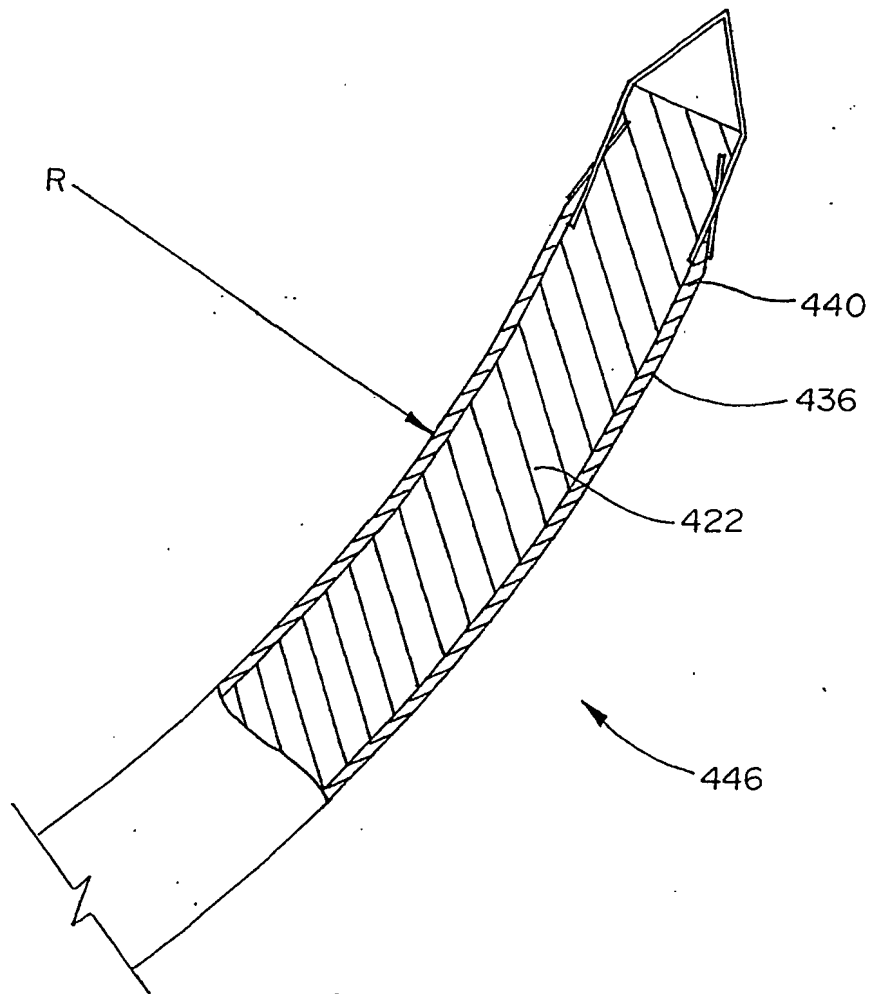


**Fig. 9**

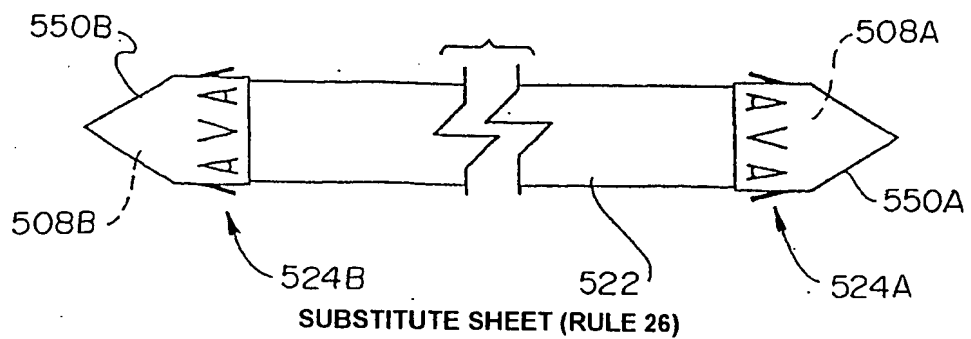


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**Fig. 10**

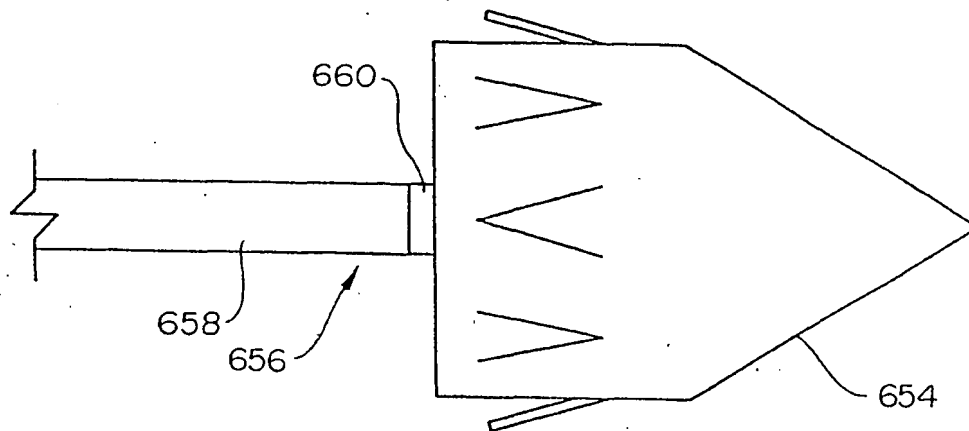


**Fig. 11**



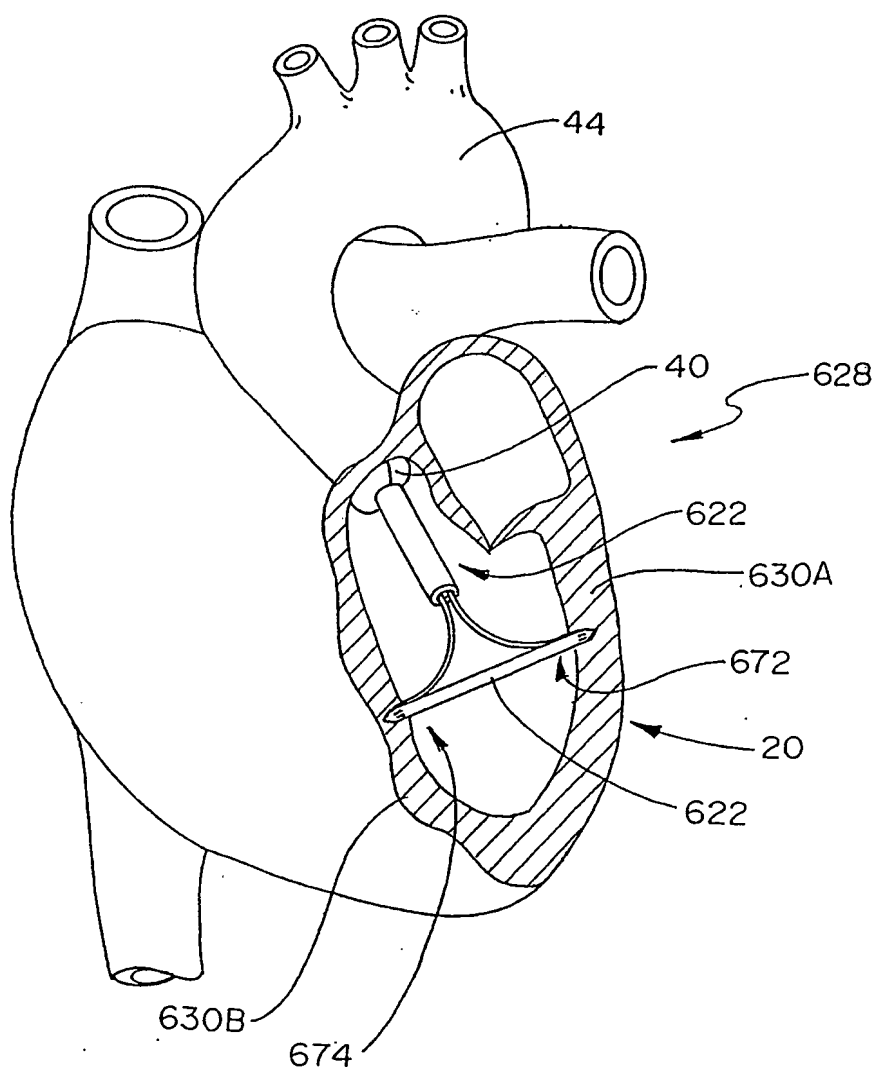
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*Fig. 13*





*Fig. 15*




## DECLARATION OF NON-ESTABLISHMENT OF INTERNATIONAL SEARCH REPORT

(PCT Article 17(2)(a), Rules 13ter.1(c) and Rule 39

Applicant's or agent's file reference <b>1001.1353111</b>	IMPORTANT DECLARATION	Date of mailing(day/month/year) <b>20/12/2001</b>
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International Patent Classification (IPC) or both national classification and IPC		A61B17/22, A61N 1/36 A61F 2/24
Applicant <b>SCIMED LIFE SYSTEMS, INC.</b>		

This International Searching Authority hereby declares, according to Article 17(2)(a), that **no international search report will be established** on the international application for the reasons indicated below

1. ☒ The subject matter of the international application relates to:
- a. ☐ scientific theories.
  - b. ☐ mathematical theories
  - c. ☐ plant varieties.
  - d. ☐ animal varieties.
  - e. ☐ essentially biological processes for the production of plants and animals, other than microbiological processes and the products of such processes.
  - f. ☐ schemes, rules or methods of doing business.
  - g. ☐ schemes, rules or methods of performing purely mental acts.
  - h. ☐ schemes, rules or methods of playing games.
  - i. ☒ methods for treatment of the human body by surgery or therapy.
  - j. ☒ methods for treatment of the animal body by surgery or therapy.
  - k. ☐ diagnostic methods practised on the human or animal body.
  - l. ☐ mere presentations of information.
  - m. ☐ computer programs for which this International Searching Authority is not equipped to search prior art.
2. ☐ The failure of the following parts of the international application to comply with prescribed requirements prevents a meaningful search from being carried out:
- ☐ the description
  - ☐ the claims
  - ☐ the drawings
3. ☐ The failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions prevents a meaningful search from being carried out:
- ☐ the written form has not been furnished or does not comply with the standard.
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4. Further comments:

Name and mailing address of the International Searching Authority  European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer <b>Johannes Van Brummelen</b>
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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 203

A meaningful search is not possible on the basis of all claims because all claims are directed to - Method for treatment of the human or animal body by surgery - Rule 39.1(iv) PCT

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.



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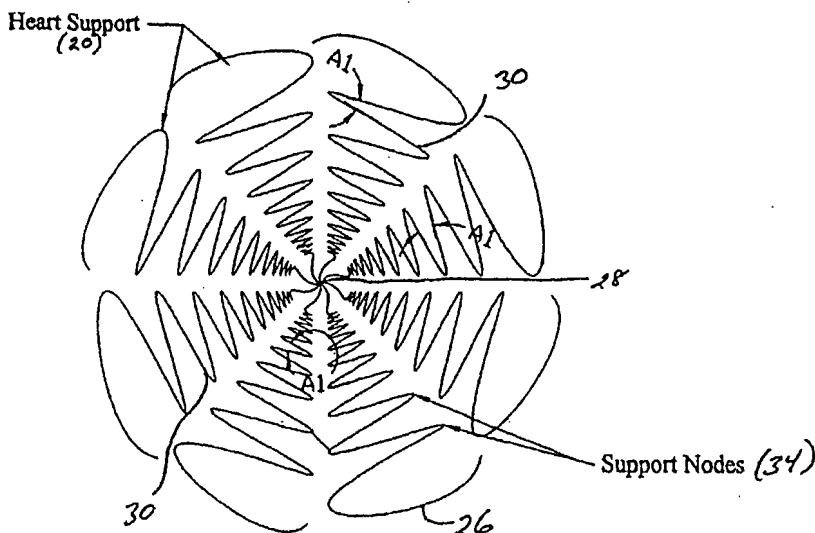
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(54) Title: HEART SUPPORT TO PREVENT VENTRICULAR REMODELING



(57) Abstract: This is a support device that prevents, reduces, and delays remodeling of diseased cardiac tissue, and also decreases the impact of such remodeling on collateral tissue is disclosed. The invention further reinforces abnormal tissue regions to prevent over-expansion of the tissue due to increased afterload and excessive wall tension. As a result, the support device prevents phenomenon such as systolic stretch from occurring and propagating. The support structure maintains and restores diastolic compliance, wall motion, and ejection fraction to preserve heart functionality. As such, the support device prevents and treats cardiomyopathy and congestive heart failure.

WO 02/19917 A1



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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

**Published:**

— with international search report

## HEART SUPPORT TO PREVENT VENTRICULAR REMODELING

5

### CROSS REFERENCE TO RELATED APPLICATION

This application claims priority to provisional U.S. Patent Application Serial Number 60/231,075, filed September 8, 2000, the entirety of which is hereby incorporated by reference.

10

### FIELD OF THE INVENTION

This invention is directed towards the transfer of energy from viable tissue regions to less viable or non-viable regions, thereby preventing, compensating for, or treating tissue responses to ischemia, infarction, or other abnormalities. In particular, this invention is directed towards the prevention, reduction, and delay of the remodeling of diseased cardiac tissue and the prevention and treatment of cardiomyopathy and congestive heart failure.

15

### BACKGROUND OF THE INVENTION

Ischemic injury causes tissue remodeling over time. This produces dyssynchronous, hypokinetic, dyskinetic or akinetic tissue function. One mechanism that perpetuates tissue remodeling (termed systolic stretch) occurs when viable ventricular tissue contracts, producing pressure that causes less viable or non-viable tissue to be forced outward. This bulging of the less viable or non-viable tissue dissipates the pumping force of the heart and adversely impacts cardiac output. The heart attempts to compensate for this decrease in cardiac output by increasing contractility and/or heart rate. However, the degree of systolic stretch progressively increases over time, continuing to reduce cardiac

20  
25

output, enlarge the volume of remodeled tissue, and exacerbate the potential for rupture of the affected tissue.

One condition that can result from such remodeling is cardiomyopathy, a typically chronic disorder of heart muscle that may involve hypertrophy and  
5 obstructive damage to the heart. A current approach for treating end-stage cardiomyopathy involves resecting a significant portion of the left ventricular free wall to reduce the size of the left ventricular cavity. The procedure, developed by Randas J. V. Batista, attempts to improve the relationship between volume, mass, and diameter. In reducing the volume of the left ventricle, investigators have  
10 observed a decrease in mitral regurgitation but a concomitant decrease in diastolic compliance. This decreases diastolic filling, which adversely impacts the complete cardiac cycle.

Other approaches for treating cardiomyopathy include reshaping the heart chambers using tethers, balloons, external bands, or other tension structures to  
15 reduce the end-diastolic diameters of the ventricles. PCT Pamphlets WO 98/29041 entitled "Heart Wall Tension Reduction Apparatus and Method"; WO 99/30647 entitled "Valve to Myocardium Tension Members Device and Method"; WO 00/06026 entitled "Heart Wall Tension Reduction Apparatus and Method"; WO 00/06027 entitled "Stress Reduction Apparatus and Method"; WO 00/06028  
20 entitled "Transventricular Implant Tools and Devices"; WO 00/16700 entitled "External Stress Reduction Device and Method" describe tethers or bands that change the geometry of the heart and restrict the maximum outer diameters of the ventricles. The tethers are positioned inside the heart and extend from one side of the ventricle to the other to exert tension on opposite sides of the heart. The bands  
25 are positioned around the epicardial surface of the ventricles and restrict expansion of the ventricles. The tethers and bands only limit local wall tension and maximal end-diastolic diameter; they do not directly assist in systolic ejection

or diastolic filling of the heart. Nor do they distribute loading over a large region of heart tissue.

### SUMMARY OF THE INVENTION

5           The present invention addresses deficiencies associated with prior approaches of purely reducing the end-diastolic diameter of the heart or preventing over-stressing of cardiac tissue. The approach described by this invention uses a heart support structure to transfer energy, in the form of contraction and expansion, from viable heart tissue to less viable or non-viable heart tissue. This structure prevents, compensates for, or treats tissue responses to ischemia, infarction, or other abnormalities.

          The embodiments of the invention maintain diastolic compliance of the cardiac tissue and synchronize the expansion and contraction of the diseased tissue to that of viable tissue in order to restore systolic ejection and diastolic filling.

15       This improves wall motion and better restores normal functionality of the heart. As a result, the embodiments of the invention prevent, reduce, and/or delay remodeling of the diseased tissue, decrease the impact of such remodeling on collateral tissue, and preserve all phases of the cardiac cycle.

          The embodiments of the invention are also useful in reinforcing abnormal tissue regions to prevent over-expansion of the tissue due to increased afterload and excessive wall tension. As a result, the dyssynchrony, hypokinesis, dyskinesis or akinesis, which occurs when tissue remodels over time, is inhibited. As such, the embodiments of the invention prevent progressive cardiomyopathy and congestive heart failure.

25       This invention provides electromagnetic assist devices that take advantage of the characteristics of the heart support structure of the invention to impart contraction and expansion throughout the heart, or along a specific region of the

ventricles. The electromagnetic assist device strategically induces magnetic fields throughout individual electromagnets coupled to the support structure, which causes an attraction or repulsion of the electromagnets and imparts a contraction or expansion of the heart support structure, and transfers such energy to cardiac  
5 tissue.

The present invention also provides enhancements to the overall system to continue to make positioning and securing the heart support structure amenable to less invasive procedures, such as endoscopic, port access approaches. In addition, the present invention enables catheterization approaches to position and secure the  
10 heart support structure.

Further features and advantages of the inventions will be elaborated in the detailed description and accompanying drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

15 Figure 1 is a side view of a heart containing a support structure of the present invention attached along an exterior portion of its left ventricle.

Figure 2 is a side view of a heart containing another support structure of the present invention attached along an exterior portion of its left ventricle.

Figure 3 is a flattened view of a heart support structure of the present  
20 invention.

Figure 4 is a flattened view of another heart support structure of the present invention.

Figure 5 is a side view of a heart containing the support structure of Figure 4 emanating from the apex of the heart.

25 Figure 6 is a side view of a heart containing the support structure of Figure 4 emanating from the ischemic or infarcted region of the heart.

Figure 7 is a flattened view of yet another heart support structure of the present invention.

Figure 8 is a side view of a heart containing the support structure of Figure 7 emanating from the ischemic or infarcted region of the heart.

5        Figure 9A is a flattened view of still another heart support structure of the present invention in its compressed state.

Figure 9B is a flattened view of the heart support structure of Figure 9A in its expanded state.

10       Figure 10 is a side view of a heart containing the support structure of Figure 9B.

Figure 11 is a side-sectional view of a heart containing support structures of the present invention along the interior surface of the left ventricle and right ventricle.

15       Figure 12A is a perspective view of an anchor used to attach the heart support structure of the present invention to tissue.

Figures 12B and 12C show top views of two additional anchor embodiments of the present invention.

Figure 12D is a side-sectional view of a heart support structure secured to a tissue surface using the anchor embodiments of Figures 12A to 12C.

20       Figure 13A is a top view of another anchor embodiment.

Figure 13B is a side-sectional view of a heart support structure secured to a tissue surface using the anchor embodiment of Figure 13A.

Figure 13C is a side-sectional view of a heart support structure secured to a tissue surface using an alternative anchor embodiment.

25       Figure 14A is a top view of another anchor embodiment.

Figure 14B is a side-sectional view of a heart support structure secured to a tissue surface using the anchor embodiment of Figure 14A.

Figure 15A is a side view of a heart containing an electromagnetically induced assist device that incorporates a heart support structure.

Figure 15B is an enlarged view of the heart support structure in Figure 15A.

Figure 16A is a side view of a heart containing an electromagnetically induced assist device that incorporates a heart support structure and is synchronized with the heart's electrical propagation.

Figure 16B is an enlarged view of the heart support structure in Figure 16A.

#### DETAILED DESCRIPTION OF THE INVENTION

The embodiments of the invention are intended to transmit energy from viable tissue regions to less viable or non-viable regions thereby preventing, compensating for, or treating tissue responses to ischemia, infarction, or other abnormalities. Ischemic injury causes tissue remodeling over time and produces dyssynchronous, hypokinetic, dyskinetic or akinetic tissue function. The embodiments of the invention prevent, reduce, and/or delay remodeling of diseased cardiac tissue, and also decrease the impact of such remodeling on collateral tissue. The embodiments of the invention are also useful in reinforcing abnormal tissue regions to prevent over-expansion of the tissue due to increased afterload and excessive wall tension. The embodiments of the invention maintain and/or restore diastolic compliance, wall motion, and ejection fraction to preserve heart functionality. As such, the embodiments of the invention prevent progression of cardiomyopathy and congestive heart failure.

The approach described by this invention, which uses a heart support structure to transfer energy (in the form of artificial contraction and expansion)



from viable heart tissue to less viable or non-viable heart tissue, addresses the deficiencies of prior approaches, which purely reduce the end-diastolic diameter of the heart. This invention aids the heart during systolic ejection and diastolic filling to better restore normal functionality of the heart. The heart support  
5 structure controls the motion of the heart and synchronizes the contraction and expansion of diseased tissue to that of viable tissue.

The heart support structure also accounts for the natural motion of the heart. As the heart contracts, the cross-sectional diameters of the ventricles decrease and the distance from the mitral valve annulus to the apex of the heart  
10 also decreases; as the heart expands, the cross-sectional diameters of the ventricles increase and the distance from the mitral valve annulus to the apex of the heart also increases. The optimal ratios of expansion (and contraction) between the cross-sectional diameters of the ventricles and the distance from the mitral valve annulus to the apex of the heart may be incorporated in the support structure to  
15 further preserve heart functionality. The heart support structure therefore preserves the wall motion and prevents remodeling of the diseased tissue by inhibiting over-expansion and maintaining normal actuation of all phases of the cardiac cycle. As a result, the dyssynchrony, hypokinesis, dyskinesis or akinesis, which occurs when tissue remodels over time, is inhibited.

20

#### Heart Support Structures

The heart support structure embodiments consist of one or more components designed to exert force against a diseased (e.g., ischemic or infarcted) region of tissue in response to the contraction or expansion of viable tissue. As  
25 such, the support structure transfers energy from viable tissue to less viable or non-viable tissue to control and force movement of injured tissue and prevent remodeling that occurs as a response to ischemic injury.

The heart support structures are preferably fabricated from superelastic (pseudoelastic) shape memory alloys, such as nickel titanium. Superelastic materials elastically deform upon exposure to an external force and return towards their preformed shape upon reduction or removal of the external force.

- 5 Superelastic shape memory alloys are capable of exhibiting stress-induced martensitic behavior; which means they transform from the preshaped austenitic phase to the softer and more ductile martensite phase upon application of stress and transform back toward the stronger and harder austenite phase once the stress is removed. Superelastic shape memory alloys enable straining the material
- 10 numerous times without plastically deforming the material. Superelastic shape memory alloys are also light in weight, biocompatible, and exhibit excellent tensile strengths such that they may be attached to the heart without substantially adding weight or bulk.

- The characteristics of superelastic shape memory alloys described above
- 15 highlight their utility in providing a support structure for the heart because they withstand continuous and frequent deflections without plastically deforming or observing fatigue failures. Superelastic support structures may also be elastically deflected into small radii of curvature and return towards their preformed configuration once the external force causing the deflection is removed. Although
- 20 other, more conventional materials such as stainless steel may be used in this application, their geometry is likely to be less fine or compact because their material properties dictate that the total elastic energy stored in a given device is much lower. Other known metal, alloy, and thermoplastic materials plastically deform when deflected into similar radii of curvature, using comparable strains,
- 25 and are unable to return towards their original configuration. As such, superelastic support structures permit deflections into smaller radii of curvature than other metals, alloys, and polymers resulting in the ability to withstand larger

strains without failing; they are also capable of exerting substantial force when deflected.

We prefer that support structures fabricated from shape memory alloys (e.g., nickel titanium) be engineered to form stress-induced martensite (SIM) at  
5 body temperature. The composition of the shape memory alloy is preferably chosen to produce martensitic transformation temperatures ( $M_s$  and  $M_f$ ) and austenitic transformation temperatures ( $A_s$  and  $A_f$ ) such that the alloy exhibits stress induced martensite up to a temperature  $M_d$ , greater than  $A_f$ .

The relative composition of nickel and titanium determines the  $A_f$  of the  
10 shape memory alloy. For example, nickel titanium having an atomic ratio of 51.2% Ni and 48.8% Ti exhibits an  $A_f$  of approximately -20 C; nickel titanium having an atomic ratio of 50% Ni to 50% Ti exhibits an  $A_f$  of approximately 100 C (Melzer A, Pelton A. "Superelastic Shape-Memory Technology of Nitinol in Medicine" *Min Invas Ther & Allied Technol.* 2000: 9(2) 59-60).

15 Preferably the composition and fabrication of the nickel titanium is chosen such that the  $A_f$  is below 32 C. Such materials are able to withstand strains as high as 10% without plastically deforming. As such, these superelastic materials are capable of elastically exerting force upon deflection.

Superelastic shape memory alloys that do not exhibit stress-induced  
20 martensitic behavior at body temperature but enable elastic deformation through the range of motion the material is exposed may alternatively be used. Materials other than superelastic shape memory alloys may be used for the support structures provided they can be elastically deformed within the temperature, stress, and strain parameters required to maximize the elastic restoring force. Such  
25 materials include other shape memory alloys, spring stainless steel 17-7, ELGILOY (Elgiloy LP, Elgin, IL), superelastic polymers, etc.

Throughout this description, discussions of external force preferably refer to the contraction and/or expansion of viable tissue causing the support structure to respond accordingly unless otherwise specified. Alternatively, another external means, artificial, biological, or a combination of artificial and biocompatible means for compressing and/or expanding the support structure may be used as will be discussed later.

Other materials may be used as a covering to the support structure, including thermoplastics (e.g., polytetrafluoroethylene or PTFE), thermoset plastics (e.g., polyethylene terephthalate, polyester), or silicone. For example, heart support structures fabricated from nickel titanium may be covered with expanded PTFE by sintering layers of expanded PTFE positioned to encompass the support structure material. Alternatively, the support structures may be coated with silicone, which when allowed to cure produces a covering over the support structure.

The heart support structure may be coated with materials such as parylene or other hydrophilic substrates that are biologically inert and reduce the surface friction. To further reduce the surface friction, metallic or metallic alloy fittings may be electropolished. Evidence suggests that electropolishing reduces adhesion because of the smooth surface and low surface tension. Alternatively, the heart support structures may be coated with heparin, thromboresistance substances (e.g., glycoprotein IIb/IIIa inhibitors), antiproliferative substances (e.g., Rapamycin), or other coatings designed to prevent adhesion, thrombosis for blood contacting support structures, hyperplasia, or other tissue response that may adversely impact the functionality of the heart support structure. Alternatively, materials such as platinum, gold, tantalum, tin, tin-indium, zirconium, zirconium alloy, zirconium oxide, zirconium nitrate, phosphatidyl-choline, pyrolytic carbon, or others may be deposited onto the heart support structure surface using electroplating, sputtering

vacuum evaporation, ion assisted beam deposition, vapor deposition, silver doping, boronation techniques, a salt bath, or other coating process.

A still further improvement of the heart support structure that is within the scope of the present invention is to include beta or gamma radiation sources on the  
5 heart support structure. A beta or gamma source isotope having an average half-life of approximately 15 days such as Phosphorous 32 or Palladium 103 may be placed on the heart support structure using an ion-implantation process, chemical adhesion process, or other suitable method.

The heart support structure embodiments may be fabricated from a sheet of  
10 material cut into the desired pattern and formed (e.g., through a heat treatment process) into the desired geometry (planar, conical, elliptical, cylindrical, or other shape). To produce these heart support structures, the raw material may be fabricated into the desired pattern by chemical etching, electron discharge machining (EDM), laser cutting, or other manufacturing process. Heart support  
15 structures fabricated from sheet stock are then wrapped or otherwise placed around mandrels having the desired resting three-dimensional profile(s) and the heart support structure is heated until it assumes this configuration. After heating, the support structure is quenched or otherwise allowed to return to room temperature, at which the support structure maintains the preformed shape. If any  
20 sides are to be bonded, spot welding, laser welding, or other manufacturing process may be employed.

Alternatively, heart support structure embodiments of the present invention may be fabricated from a tube of material having a desired cross-sectional geometry. The desired pattern of links, anchors, anchor pins, holes,  
25 slots, and/or cells may be fabricated on the tubular metal material and may be created using chemical etching, EDM, laser cutting, or other manufacturing process. These heart support structures may be thermally formed into the desired

planar or three-dimensional profile depending on the desired shape of the heart support structure.

Figure 1 shows a heart containing a support structure 20 secured to the epicardial surface at specific attachment points 22 along a section of the left ventricle (LV) 2. A tissue interface 18 may or may not be positioned between support structure 20 and the epicardium, as will be discussed below. In this particular embodiment, peripheral links 26 extend around the injured tissue 24 (e.g., ischemic or infarcted). Support links 30 extend from peripheral links 26 into the injured tissue 24 to provide the structure from which contraction and/or expansion energy may be transferred from peripheral links 26 to a central region 28 of the support structure located throughout the injured tissue 24. The geometry of support structure 20 depends on the location of the injured tissue. If the injured tissue 24 is on the left ventricular free wall, support structure 20 may be planar or have a slightly curved three-dimensional profile. If the injured tissue 24 is apical, support structure 20 may be generally conical or approximate one half of an ellipsoid.

The support structure embodiment in Figure 1 is secured to the left ventricle at desired locations throughout a central region 28 within the injured tissue 24, and along peripheral links 26 and/or support links 30. Central region 28 of the support structure may be a discrete point or a two-dimensional surface, or it may constitute a region of multiple intersecting, interlocking, or adjacent support links 30. Central region 28 shown in Figure 1 consists of four intersecting support links 30; we prefer that a minimum of two intersecting support links 30 be used for this configuration.

Each support link 30 extends from at least one peripheral link 26 located past one end of the injured tissue 24, and attached to viable tissue, to at least one peripheral link 26 located past the opposite end of the injured tissue 24, and

attached to viable tissue. An alternative configuration involves individual support links that terminate at the central region 28 and are not attached to the other independent support links throughout the central region 28 or using peripheral links.

5           Peripheral links 26 and support links 30 in the embodiment of Figure 1 are designed for different purposes. Support links 30 are designed to cause corresponding movement of the injured tissue 24 in response to contraction or expansion of the viable tissue to which support links 30 are secured. As such, the support links require sufficient axial stiffness to contract or expand the injured  
10       tissue 24 in response to movement of the proximal ends of the support links located along peripheral links 26 of support structure 20. Support links 30 must also have sufficient flexibility so that they do not hinder movement of viable tissue between central region 28 and peripheral links 26 of the support structure. Peripheral links 26 must be flexible so to be able to move coincident with  
15       contraction and expansion of the left ventricle, and durable enough to maintain the integrity of heart support structure 20 despite continued movement of the support structure.

          Figure 2 shows a heart containing another support structure embodiment 20 emanating from a central region 28, located within injured tissue 24. The  
20       peripheral links 26 for this embodiment do not extend completely around the injured tissue, but connect adjacent support links 30 at their proximal ends and are attached to viable tissue. Support links 30 interconnect in central region 28 and the unions are secured to the injured tissue 24 at attachment points 22. Support links 30 in this embodiment also interconnect along a middle section 32 located  
25       between central region 28 and the periphery of the support structure. Middle section 32 unions are also secured to the tissue surface at attachment points 22.

It should be noted that middle section 32 may be located along central region 28, anywhere between central region 28 and peripheral links 26, and/or along the proximal end of the support structure defined by peripheral links 26. Different middle sections 32 may be positioned at different locations along the tissue surface, depending on the axial stiffness and flexibility requirements of support links 30.

Figures 3 and 4 show flattened profiles of two alternative support structures of the present invention. Support structures 20 incorporate eight support links 30 that extend from a central point 28 and snake towards peripheral links 26; a minimum of two support links 30 are used to form this support structure embodiment. Each turn of a snaking support link 30 defines a node 34. The relation of the support links to the nodes defines the stiffness profile of support structure 20. In Figure 3, support nodes 34 are separated such that the angle A1 between adjacent turns of each snaking support link 30 is constant. In Figure 4, the distance H1 between adjacent support nodes 34 is constant.

The parameters of each support link 30 (width, wall thickness, total length, and turn length) also influence the stiffness. The stiffness profile of the support structure determines the degree of contraction and expansion transferred from viable tissue to injured tissue 24 throughout the support structure 20. This profile may be optimized depending on the anticipated position of various support links 30 relative to anatomic structures and desired responses.

For example, the apex of the heart contracts and expands at a different degree than the left ventricular free wall; the right ventricle (RV) is much more compliant than the left ventricle. As such, support structure 20 must incorporate such profiles to maximize the restoration of systolic ejection and diastolic filling. More than one target zone of injured tissue may be addressed with a single support structure or multiple support structures by tailoring the stiffness profile(s)



of the support structure(s) to ensure the desired contraction and expansion force is transferred and distributed throughout the surface of the targeted tissue surface.

Figure 5 shows the support structure shown in Figure 4 thermally formed into a conical geometry and positioned such that central region 28 (in this case a point) is located at the apex 14 of the heart. As will be discussed later, a tissue interface is positioned between support structure 20 and the tissue surface. This support structure 20 is secured to the tissue surface at attachment points 22 in central region 28, interspersed throughout nodes 34 along support links 30, and along peripheral links 26. This support structure embodiment is configured to treat apical infarcts or ischemic regions and/or cover both ventricles. As previously discussed, discrete support links 30 may be fabricated with various parameters (width, wall thickness, length), node separation (H1), or turn length to impart different stiffness profiles throughout the heart.

For example, support links 30 positioned along the right ventricle 4 require substantially less stiffness than those positioned along the left ventricle 2 to impart the same amount of contraction and expansion in the right and left ventricle respectively. In addition, the amount of contraction and expansion for the right ventricle differs from that for the left ventricle, thus the stiffness profile of apically positioned support structures must account for the disparity.

Figure 6 shows the support structure of Figure 4 emanating from a central region 28 positioned within injured tissue 24 located along the left ventricular free wall. Support links 30 extend from a point at central region 28 and extend to peripheral links 26 positioned at a desired distance beyond the injured tissue 24. This particular support structure is configured to isolate the transfer of contraction and expansion energy from viable tissue, residing outside a border zone of injured tissue 24, to injured tissue 24.

Figure 7 shows an alternative support structure embodiment that interconnects support links 30 around a circle or other shape used to define central zone 28. Support links 30 are tapered from peripheral links 26 to central zone 28. Support links 30 may be tapered in width (as shown in Figure 7), wall thickness, and/or other parameters capable of influencing the structure's axial stiffness and flexibility along the length of support link.

As previously stated, individual support links 30 may incorporate different stiffness characteristics to tailor the stiffness profile of the support structure to the physiologic requirements. The proximal ends of the support links 30 are attached to the peripheral links 26 such that the intersection forms anchors 52 or defines an attachment point. Peripheral links 26 are configured significantly more flexible than support links 30 since peripheral links 26 maintain the integrity of support structure 20 but do not transfer energy throughout tissue encompassed by the support structure.

Figure 8 shows a heart that contains the support structure embodiment of Figure 7. Central zone 28 is located along the injured tissue region 24. The individual peripheral links 26 extend completely around the injured tissue region 24 at distances defined by the individual support links 30. These distances may be constant or may vary by changing the length and/or shape of each support link 30. The distances between peripheral links 26 and central zone 28 also impact the stiffness profile of the support structure and influence the transfer of contraction and expansion energy from viable tissue to the injured tissue zone 24.

The central zones of the various support structure embodiments discussed above may be integral to support links 30 or alternatively may be comprised of one or more separate components that are attached to the support links. This separate component(s) may be fabricated from the same material as the support links or a different material. For instance, compliant materials such as silicone,

urethane, or other biological materials having high percent elongation characteristics may be used.

Figures 9A and 9B show an alternative support structure embodiment that causes the width to expand as the length expands (or vice versa) and causes the width to contract as the length contracts (or vice versa). For example, as an external force causes the length of the support structure to expand from position A1 to position A2, the width of the support structure expands from position B1 to position B2. The external force described in this embodiment may be, for example, movement of viable tissue. The expansion or contraction energy is transferred from the actuated section of the support structure throughout the remainder of the support structure causing cardiac tissue, to which the support structure is attached, to expand or contract accordingly.

The characteristics of this support structure are substantially different than the flattened profile of any prior stent or stent-graft. Conventional stents or stent-grafts contract or minimally change in length as the diameter is expanded. Stents or stent-grafts fabricated with the support structure geometry shown in Figure 9A and 9B expand in length as the diameter is expanded. As such the support structure embodiment in Figures 9A and 9B may be fabricated as a complete tube and used as a stent or stent-graft (if the support structure is attached to at least one end of graft material).

The support structure embodiment shown in Figures 9A and 9B incorporates cells 40 interconnected by horizontal links 38 and vertical links 36 that are attached to the cells at nodes 42. The cells also incorporate hinges 44 to permit expansion and contraction of the cells 40 in response to an external force. As the width (or length) of each cell expands from W1 to W2 (or L1 to L2), cell nodes 42 located at vertical links 36 and horizontal links 38 are deflected outward, about hinges 44, thereby causing the length (or width) of the cell to also expand

from L1 to L2 (or W1 to W2). This transfers the expansion force to adjacent cells, thereby propagating the expansion throughout the support structure. The converse is also true: as the width (or length) of each cell contracts from W2 to W1 (or L2 to L1), the nodes are deflected inward, causing the length (or width) of the cell to  
5 also contract from L2 to L1 (or W2 to W1) and transferring the contraction force to adjacent cells.

The support structure embodiment of Figures 9A and 9B is shown as having arrays of cells positioned equidistant along its the width and length, where each cell has a constant width and length in the relaxed position. Alternatively,  
10 the cells may be positioned such that vertical links 36 and horizontal links 38 are generally not perpendicular. As such, the length L1 (or width W1) of each cell may be decreased along the width B1 (or length A1) of the support structure to produce a taper along the width (or length) of the support structure.

Other combinations of cell widths W1 and lengths L1 may be used to tailor  
15 the stiffness and degree of ratio of expansion between the width and length for the support structure to the geometry of the heart and the amount of expansion and contraction desired throughout the support structure.

For example, to tailor this support structure embodiment so it may be positioned apically, length A1 of the support structure may be tapered along width  
20 B1 such that the length of each cell L1 decreases at specified intervals and/or the length of each horizontal link 38 decreases. Such modifications potentially impact the stiffness profile of the support structure; therefore, cell width T1, horizontal link width T2, vertical link width T3, and/or wall thickness of each cell and link may be decreased as the cells are tapered so as to compensate for the increase in  
25 stiffness associated with decreasing the cell dimensions.

Cell width T1, horizontal link width T2, vertical link width T3, and/or wall thickness of each cell and link may alternatively be varied to predefine the

stiffness profile of the support structure, accommodate nonlinear expansion or contraction requirements throughout the ventricles, or address anatomic variances that warrant changes in support structure geometry or stiffness.

Figure 10 shows a heart with the support structure embodiment of Figure 9B attached to the left ventricle. Support structure 20 is centered around the injured tissue region 24 to optimally transfer the expansion and contraction forces from viable tissue to the injured tissue 24. The support structure embodiment of Figure 10 is shown in the enlarged configuration, reflecting the end-diastolic orientation and geometry of the support structure.

Positioning and securing support structure 20 to the surface of the heart chamber is preferably performed with the heart at end-diastole and with the support structure in the enlarged orientation (either by preshaping or manually stressing). In certain scenarios, the support structure may be configured to exert some contractile force throughout the cardiac cycle, even during end-diastole. To accomplish this, the support structure is positioned and secured to the tissue surface during end-diastole with the support structure stressed into its expanded orientation. Securing the support structure to the heart during end-diastole ensures better seating against the ventricle and the observed spacing between attachment points 22 ensures optimal transfer of contraction and expansion energy from the support link attachment points to the injured tissue 24.

It should be noted that the steps of positioning and securing support structure 20 to the tissue surface may alternatively be performed at end-systole with support structure 20 in the contracted orientation, or at any phase in the cardiac cycle. It should also be noted that the positioning and design of the support structure may bias the structure such that a continuous contractile force exerted by the elasticity of the support structure is applied even during end-diastole, a continuous expansion force is applied even during end-systole, or a

contractile force is applied during relaxation and diastolic filling and an expansion force is applied during contraction and systolic ejection.

The embodiments described above show the support structure attached to the epicardial surface of the ventricles. Alternatively, as shown in Figure 11, at  
5 least one support structure 86 and/or 88 may be secured to the endocardial surface of at least one of the left ventricle 2 and the right ventricle 4. Any of the support structure embodiments described above may be modified to enable positioning the support structure against the endocardial surface. For purposes of discussion, the embodiment of Figure 4 is shown as the left ventricular support structure 86 and  
10 the right ventricular support structure 88 in Figure 11. The support structures 86 and 88 are configured such that the central regions 28 of each is located at the apex 14 of the left ventricle 2 and right ventricle 4.

The LV support structure 86 is preferably preshaped to match the end-diastolic geometry and optimal size of the left ventricular cavity. Peripheral links  
15 26 and support links 30 of LV support structure 86 do not interfere with the operation of mitral valve 48, the papillary muscles, or the chordae tendonae. Support links 30 may be fabricated with spaces where the papillary muscles extend into the left ventricular cavity and where the chordae tendonae extend from the papillary muscles and connect to mitral valve 48. Support links 30 are  
20 distributed throughout the endocardial surface of the left ventricle extending from the interventricular septum 46 completely around the left ventricular free wall. As such, injured tissue regions extending into or located along the interventricular septum may be covered by support structure 86. Alternatively, the left ventricular support structure 86 may be designed to cover only the interventricular septum,  
25 the left ventricular free wall, or other endocardial tissue region.

The RV support structure 88 is preferably preshaped to match the end-diastolic geometry and optimal size of the right ventricular cavity. Peripheral

links 26 and support links 30 of RV support structure 88 do not interfere with the operation of the tricuspid valve 50, the papillary muscles, or the chordae tendonae. Support links 30 may be fabricated with spaces where the papillary muscles extend into the right ventricular cavity and where the chordae tendonae extend

5 from the papillary muscles and connect to the tricuspid valve 50. Support links 30 are distributed throughout the endocardial surface of the right ventricle extending from the interventricular septum 46 completely around the right ventricular free wall. As such, injured tissue regions extending into or located along the interventricular septum may be covered by the support structure 86. Alternatively,

10 the right ventricular support structure 86 may be designed to cover only the interventricular septum, the right ventricular free wall, or other endocardial tissue region. For injured tissue isolated within the interventricular septum, the right ventricle is the preferred location to position and secure a support structure against the endocardial surface in which the support structure is designed to solely cause

15 expansion and contraction of injured tissue along the interventricular septum.

Support structures located along the endocardial surface of the right and/or left ventricle may be combined with support structures located along the epicardial surface to enhance the transfer of energy from viable tissue to less viable or non-viable tissue, especially when several injured tissue regions are dispersed

20 throughout the heart. The support structures may be independent such that the endocardial support structures are not attached to the epicardial support structures. Alternatively, individual support links of the endocardial support structures may be inserted through the myocardium and may be connected to epicardial support structures so as to interconnect the expansion and contraction of the endocardial

25 support structures to the epicardial support structures. This is especially relevant when the injured tissue extends from the interventricular septum to the left ventricular free wall and the desired position of the support structure extends from

the right ventricular endocardial surface of the interventricular septum through the myocardium of the right ventricle and along the epicardial surface of the left ventricle. Other combinations of endocardially and epicardially positioned support structures may be used to address other indications or injured tissue  
5 locations.

The various support structure embodiments described above exhibit isotropic, orthotropic, or anisotropic structural properties. It should be noted that the embodiments of the invention may be modified to exhibit different structural properties (isotropic, orthotropic, or anisotropic) to match the inherent structural  
10 properties of the tissue surface to which the support structure encompasses, or to tailor the support structure to specific tissue surface locations. They may also be configured to modify the structural properties of the tissue surface to reduce wall tension, improve contractility, or otherwise change the functionality of the heart. It should also be noted that the structural properties of the support structures  
15 described above may be modified to address other applications as are known to those of skill in the art.

#### Support Structure Anchoring

The heart support structures described above typically are secured to the  
20 epicardial surface and/or endocardial surface at attachment points 22. A variety of bonding methodologies may be employed including adhesives (fibrinogen, etc.), coagulating the surface to the support structure by heating the tissue, or mechanically anchoring the support structure to the tissue surface, a technique that is discussed below. The support structures may incorporate anchors that penetrate  
25 into tissue, holes to pass suture, flaps that become entangled in the trabecula of the ventricles for endocardial support structures, or other mechanical securing mechanism with which to attach the heart support structure to the tissue surface.



The heart support structure is alternatively secured to the tissue surface using commercially available implantable clips, staples, or other means.

Figure 12A shows a support structure 20 that incorporates an anchor 52 designed to penetrate into tissue. Anchor pins 54 extend radially away from anchor 52 at acute angles to maintain the position of the anchor within the tissue surface, once positioned. Anchor pins 54 may extend from the anchor in curves as shown in Figure 12B, along lines as shown in Figure 12C, or in other orientations. As shown in Figure 12D, support structure 20 is secure to the tissue surface after anchor 52 is inserted through the first heart surface (epicardium 60 or endocardium 58) and anchor pins 54 are constrained from axial movement by the myocardium 56.

Alternatively, the anchor may be inserted past the first heart surface (epicardium 60 or endocardium 58), through the myocardium 56, and past the second heart surface (endocardium 58 or epicardium 60) such that the anchor pins are constrained by the second heart surface. As shown in Figure 12D, a tissue interface 18 spaces the support structure from the tissue surface, as will be described in detail below; even so, tissue interface 18 must enable insertion of the anchor during positioning and securing of the support structure.

During deployment, anchor pins 54 may be constrained with a delivery tube or may be allowed to deflect into a reduced diameter as the anchor is inserted through the tissue surface (and tissue interface 18, if any). The outward bias of anchor pins 54 causes them to extend radially once positioned within the myocardium and prevent pulling the anchor away from the tissue surface. The anchor shown in Figures 12A to d may be fabricated from as a separate component that is bonded (e.g., spot welding, soldering, adhesive bonding, or other suitable attachment means) to the links of the support structure at predefined locations. Alternatively, the anchor may be cut (e.g., laser cutting, EDM,

chemical etching, water jet cutting, or other suitable process) from links in the support structure and thermally formed into the desired anchor and anchor pin shapes.

Figures 13A to 13C show an alternative anchor 52 embodiment. This anchor 52 shapes anchor pin 54 into a screw configuration such that the anchor is inserted through the tissue surface 60 or 58 (and the tissue interface 18, if any) as the anchor is rotated. This anchor 52 may be a separate component that is independently rotatable relative to the links of support structure 20, as shown in Figure 13A. As such, a screw head 62 may be formed in the proximal end of the anchor and used to rotate the anchor relative to the links of the support structure 20. Alternatively, the anchor pin may be integral to the links of support structure 20 and are straightened in a delivery tube for insertion through the tissue surface 60 or 58 (and the tissue interface 18, if any). The delivery tube is removed from around the anchor pin, allowing the anchor pin to return towards its preformed shape once positioned in the myocardium 56.

The anchor pin of these embodiments may be configured with alternative geometries to facilitate deployment and/or attachment of the support structure to the tissue surface. For example, a single anchor pin may extend from the anchor as a hook which is capable of being inserted through the tissue surface by angling the anchor pin such that the distal tip penetrates through the tissue surface and advancing the rest of the anchor.

The anchors described previously may also be connected to an electrosurgical generator capable of transmitting radio frequency (RF) energy to tissue contacting the anchors. As such, tissue adjacent the anchors resistively heats in response to exposure to the RF energy, causing the tissue to coagulate to the anchors and enhance the bond between the anchors (and thus the support structure) and the tissue surface.

As shown in Figures 14A and 14B, holes 64 may be incorporated in the links of support structure 20 such that commercially available suture 66 (alternatively, clips or staples) may be inserted through one hole 64, past the tissue surface 60 or 58, partially through the myocardium 56, back through the tissue surface 60 or 58, and back through the second hole 64. Once positioned, suture 66 is tied thereby securing the link of the support structure to the tissue surface. Alternatively, suture 66 may be inserted through only one of the holes 64, or the suture 66 may be passed around the width of a support structure link where no holes are required.

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#### Tissue Interface

As shown in Figures 12D, 13B, and 14B, tissue interface 18 spaces support structure 20 from the surface of the heart (60 or 58), and inhibits abrading the surface of the heart due to components of the support structure moving along the surface of the heart. Tissue interface 18 may be a synthetic graft material, harvested biological material, or other lubricious structure.

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Alternatively, tissue interface 18 may be a spacer 90 incorporated in support structure 20 at attachment point 22 to maintain separation between the epicardium 60 or endocardium 58 and the links of support structure 20, as shown in Figure 13C. Spacers 90 are preferably thermally preformed sections in the support structure located at the anchors 52, or desired attachment point 22, such that the links of the support structure are biased away from the tissue surface 60 or 58.

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The support structure does not move relative to the tissue surface 60 or 58 at the anchors and/or attachment points; therefore, the support structure may directly contact the tissue surface at those locations, realizing that the support structure will endothelialize or epithelialize at the locations where the support

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structure is in intimate tissue contact. For support structures that completely reflect motion of the heart throughout the surface of the support structures, the entire support structure may be placed into intimate contact with the tissue surface 60 or 58 and allowed to epithelialize or endothelialize and become integral with  
5 the heart.

The harvested biological material is preferably a section of the pericardium, which may be cut away, sized relative to the heart support structure, and positioned between the support structure and the epicardium. Other tissue such as submucosal tissue (e.g., that obtained from the small intestine or other  
10 body organ) may be harvested, formed into the desired geometry, and used as the heart interface. The use of submucosal tissue is described in WO 98/19719 by Geddes, et al, entitled "Myocardial Graft Constructs", the entirety of which is incorporated herein by reference. Other biological materials such as collagen may alternatively be formed into the desired geometry and used as the heart interface.

15 The primary advantage of using biological tissue interface materials over currently available synthetic materials is the reduction in adhesions, thrombosis for tissue interfaces that are exposed to blood flow, or other tissue response that may adversely impact the function of the heart support structure. However, the heart support structure embodiments of the invention are equally effective at  
20 utilizing all types of tissue interface materials, biological and synthetic.

Synthetic tissue interface materials may be manufactured by extruding, injection molding, weaving, braiding, or dipping polymers such as PTFE, expanded PTFE, urethane, polyamide, polyimide, nylon, silicone, polyethylene, polyester, PET, composites of these representative materials, or other suitable  
25 graft material. These materials may be fabricated into a sheet, tubing, or other three-dimensional geometry using one or a combination of the stated manufacturing processes. Tubing materials may be along at least one side to form

a flattened profile. The synthetic bypass graft may be coated, deposited, or impregnated with materials, such as parylene, heparin solutions, hydrophilic solutions, thromboresistance substances (e.g., glycoprotein IIb/IIIa inhibitors), antiproliferative substances (e.g., Rapamycin), or other substances designed to  
5 reduce adhesions, thrombosis (for heart interfaces exposed to blood flow), or mitigate other risks that potentially decrease the functionality of the heart support structure. In addition, synthetic bypass grafts may be seeded with endothelial cells or other biocompatible materials that further make the inner surface of the bypass graft biologically inert.

10

#### Deployment Systems

Surgical positioning and securing of the heart support structures described above to the epicardial tissue surface 60 involves a relatively large incision through the thoracic cavity to expose the heart. Surgical intervention enables  
15 accurate positioning and assures optimal securing of the support structure relative. During open heart surgery, direct access to the epicardial surface of the heart enables suturing or adhesively bonding the support structure to the heart; as such, alternative anchoring mechanisms described above are not necessarily required. However, such anchoring mechanisms may provide benefit in reducing the time to  
20 attach the support structure to the surface of the heart or improve the expanded (or contracted) orientation of the support structure relative to the end-diastolic (or end-systolic) orientation of the heart.

The support structure embodiments discussed in this invention are directly amenable to less invasive (i.e. minimally invasive) surgery involving a  
25 thoracostomy or mini median sternotomy to access the heart and endoscopes to visualize the thoracic cavity.

The deployment system for such reduced access surgical applications leverages conventional port access techniques to produce an opening through the thoracic cavity. Trocars are commonly used to gain access into the thoracic cavity after puncturing through the intercostal space. Once the ports into the thoracic  
5 cavity are defined, the parietal pericardium is cut and the incision is extended to expose the epicardial surface of the heart. As previously stated, the pericardium may be used as the tissue interface between the support structure and the epicardial surface of the heart.

The support structure is compressed into a reduced diameter by rolling for  
10 relatively planar support structures, or folding, stretching, or otherwise bending for more three-dimensional support structures. The compressed support structure is positioned in a delivery sheath designed to feed the support structure past the port. Once inside the thoracic cavity, the support structure is expelled from the delivery sheath, at which point it expands towards its preformed resting shape.

15 At this point, the support structure is lined up relative to the desired epicardial location and individual anchors are positioned through the tissue surface to secure the support structure to the tissue surface at each attachment point. As previously stated, alternative securing modalities may be used including adhesives, suture, thermal coagulation, implantable clips, staples, or other  
20 mechanism.

Conventional forceps, hemostats, and clamps are used to position the anchors. Alternatively, delivery tubes may compress the anchor pins into a reduced diameter for insertion through the tissue surface. In such a case, the delivery tubes are beveled at their distal ends to penetrate through the tissue  
25 surface and to provide a conduit to insert the anchor and position the anchor pin or pins into the myocardium.

When positioning the individual anchors at each attachment point, the support structure is continuously lined relative to the epicardial surface and at end-diastole and the anchors are inserted through the tissue surface. This ensures the support structure is positioned in its expanded orientation against the ventricles in  
5 their expanded orientation producing a better match between the expansion and contraction properties of the support structure to that of the ventricles. When lining the anchors of the support structure, the support links may need to be stressed or preformed into their expanded orientation to ensure the support links are appropriately lined up relative to the end-diastolic heart. As previously stated,  
10 the support structure may alternatively be attached to the heart during end-systole; at which case, the support structure is stressed or preformed into its contracted orientation during the attachment process. Alternatively, the heart may be temporarily stopped while securing sections of the support structure to the epicardial surface.

15 When positioning the support structures against the endocardial surface, catheters are used to compress the support structure into a reduced diameter. The catheters may be inserted percutaneously into the venous or arterial vasculature and routed to the desired heart chamber. To access the left ventricle, a catheter is routed through the femoral or brachial artery, around the aorta, past the aortic  
20 valve and into the left ventricle. Alternatively, the catheter is passed through the femoral or subclavian vein, into the right atrium, past the interatrial septum (by use of a transseptal technique), into the left atrium, past the mitral valve annulus, and into the left ventricle. To access the right ventricle, the catheter is passed through the femoral or subclavian vein, into the right atrium, past the tricuspid  
25 valve, and into the right ventricle.

Once in the desired heart chamber, the catheter is positioned at the apex of the ventricle. The support structure is compressed within the catheter by folding,

stretching, or otherwise bending the support structure prior to inserting the catheter to the desired heart chamber. The support structure forms a three-dimensional geometry that closely matches the endocardial surface (either at end-diastole or end-systole). The anchors of the support structure may contain flaps  
5 intended to become entangled in the trabecula of the ventricles or anchor pins capable of becoming constrained in the myocardium once the anchor has penetrated through the endocardial surface. A plunger, in the form of a second steerable catheter, may be used to urge the anchors into position. Alternatively, the delivery catheter may be used as the plunger.

10 If any are used, the sheath and dilators of the deployment systems may be constructed from polyethylene, polycarbonate, thermoplastic (such as PEEK, manufactured by Victrex PLC, United Kingdom), other polymer, metal, or metal alloy that may be extruded, injection molded, or swaged into a tube having the desired cross-sectional profile. A taper and radius may be formed in the  
15 components of the deployment system by thermally forming the tubing into the desired shape or incorporating such features in the injection molding cast. In addition, the components of the deployment system may incorporate a softer distal tip fabricated by thermally bonding a short section of lower durometer tubing to the sheath or tapering the thickness of the sheath tubing.

20 To prevent the backflow of blood through deployment sheaths, hemostatic valves may be used. The hemostatic valves prevent blood leakage but permit insertion of the support structure through the sheath.

#### Electromagnetic Assist

25 It is within the scope of this invention to provide electromagnetic assist devices that take advantage of the characteristics of the heart support structure of the invention to impart contraction throughout the heart or along a specific region



of the ventricles. These devices strategically induce magnetic fields throughout the heart support structure to impart an expansion or contraction of the heart support structure, which then transfers energy to the heart chambers.

The electromagnetic assist device may function independent from the  
5 natural contraction of the heart chambers to completely control the timing of isovolumetric ventricular contraction, systolic ejection, isovolumetric relaxation, and diastolic filling. Alternatively, the electromagnetic assist device may be synchronized to the inherent electrical propagation of the heart, which passes from the SA Node through the atria along the AV Node and through the ventricles. In  
10 doing so, the electromagnetic assist device times each phase of the cardiac cycle, as artificially created using the heart support structure, relative to the inherent electrical propagation of adjacent cardiac tissue, thereby preserving the natural motion of the heart and responding to biological stimuli for changing heart rate.

Figure 15A shows a heart containing a support structure 20 that  
15 incorporates electromagnetic coils 72 strategically positioned throughout the links of the support structure. The embodiment of Figure 15A is the same as that of Figures 9A and 9B. Alternatively, previously described support structures may be used, provided they incorporate links to which the electromagnetic coils 72 may be attached and used to induce a magnetic field designed to impart a contraction  
20 or expansion of the support structure.

U.S. Patent 6,099,460 to Denker, incorporated herein by reference in its entirety, a heart that is artificially forced to contract in response to magnetic fields induced by electromagnets positioned on the exterior surface of the heart and/or interior of the heart. The '460 patent does not incorporate a support structure to  
25 provide optimal contraction and expansion, but relies solely on the attraction of the electromagnets positioned on opposite sides of the heart chambers. In addition the injured or diseased tissue contracts differently than viable tissue thus

continuing to propagate the tissue remodeling of the injured or diseased tissue. In addition, the '460 patent does not teach assisting in the diastolic filling of the heart, and therefore excludes one important phase in the cardiac cycle.

Electromagnetic cores 74 are positioned over horizontal links 38 of support structure 20, as shown by an enlarged view of the support structure in Figure 15B. Electromagnetic coils 72 are wound around electromagnetic cores 74 and are routed to electromagnetic source 68 either directly or via polarity switching unit 70 as shown in Figure 15A. The leads of electromagnetic coils 72 that are directly connected to the electromagnetic source are either connected to the positive terminal 76 via positive lead 76 signal wires or the negative terminal 78 via negative lead 78 signal wires. The leads of electromagnetic coils 72 that are connected to the polarity switching unit 70 are either connected to OUTA terminal 80 via lead (A) 80 signal wires or the OUTB 82 terminal via lead (B) 82 signal wires. Polarity switching unit 70 is connected to the positive and negative terminals of electromagnetic source 68. The polarity switching unit and the electromagnetic source may also be grounded together. Polarity switching unit 70 changes the OUTA connection from the IN+ (that is routed to the positive terminal) to the IN- (that is routed to the negative terminal) and vice versa.

Simultaneously, polarity switching unit 70 changes the OUTB connection from the IN- to the IN+ and vice versa. In switching the positive and negative connections of an electromagnetic coil 72, the induced magnetic field along the electromagnetic coil alters its polarity accordingly. As such, the response of adjacent coils to the specific polarity protocol may be specified to selectively produce an attraction between adjacent electromagnets, thereby causing a contraction of the heart support structure, or to induce a repulsion between adjacent electromagnets thereby causing an expansion of the heart support structure. The ability to switch the polarity of at least one set of electromagnetic

coils 72 enables producing both an attraction and a repulsion thereby covering the complete cardiac cycle. The embodiment shown in Figure 15A maintain the polarity of a group of electromagnetic coils 72 constant and changes the polarity of adjacent electromagnetic coils 72 to impart the attraction or repulsion force.

5           The period and amplitude of each pulse transmitted from the electromagnetic source (directly or via the polarity switching unit) to the electromagnetic coils determines the amount and duration of the attraction or repulsion force imparted to heart support structure 20 by the electromagnetic assist device. Support structure 20 is essential to the electromagnetic assist device in  
10       that it provides enhanced control to and enables variability in the expansion and contraction throughout the surface of the heart. Changing the stiffness profile of the support structure 20 throughout the surface of the heart is more sensitive and effective than varying the degree of attraction and repulsion between adjacent magnets.

15           Figure 16A shows a heart incorporating another electromagnetic assist device embodiment. This embodiment has a different support structure 20 embodiment attached only around the injured or diseased tissue. As such, the response of the electromagnetic assist device must be synchronized with the inherent electrical propagation throughout the heart. Figure 16B shows an  
20       enlarged view of the heart support structure in Figure 16A. Support structure 20 incorporates horizontal links 38 and vertical links 36 that interconnect electromagnetic cores 74 and associated electromagnetic coils 72. As described above, leads (76, 78, 80, or 82) of electromagnetic coils 72 are routed to terminals (positive or negative) on electromagnetic source 68 or to terminals (OUTA or  
25       OUTB) on polarity switching unit 70, which are routed to the terminals (positive or negative) on the electromagnetic source 68.

As shown in Figure 16A, a pacing controller 92 is connected to amplitude control 96 of the electromagnetic source 68 and timing control 94 of polarity switching unit 70. Electrodes 98 and 100 are secured to the right atrium and left atrium respectively and atrial signals are transmitted to pacing controller 92 which  
5 can acquire the atrial electrograms. Ventricular signals from electromagnetic coils 72 may be transmitted through electromagnetic source 68 and/or polarity switching unit 70 to pacing controller 92 which can filter the ventricular electrograms. Pacing controller 92 utilizes the atrial and ventricular electrograms to determine the activation of heart support structure 20 by controlling the  
10 amplitude of the electromagnetic source and the switching of the magnetic field polarity. In this way, the contraction and expansion of the heart support structure may be synchronized with the natural movement of the heart.

#### Other Artificial Assists

15 The heart support structure embodiment shown in Figures 9A and 9B is described as a potential support structure for the electromagnetic assist device shown in Figure 15A. This support structure embodiment may also be used in an assist device where an artificial external force other than electromagnetic induction is used. The predetermined response between the expansion (or  
20 contraction) of the width (or length) and the corresponding expansion (or contraction) of the length (or width) makes this support structure particularly amenable to an artificial external force that expands and/or contracts a first dimension and relies on the support structure to impart the expansion or contraction force to a second dimension. Of course, the first dimension and/or the  
25 second dimension described above may vary throughout the support structure. A linearly actuated external force may be used to expand or contract a discrete

section of the support structure, relying on the support structure to transfer the expansion or contraction energy throughout the remaining support structure.

One such artificial external force involves attaching a length of skeletal tissue to a section of the support structure and causing the skeletal tissue to  
5 contract and relax in response to pacing stimuli. This linear contraction and expansion is transferred throughout the entire support structure to impart the desired three-dimensional contraction and expansion responses.

Another artificial external force involves any type of motor capable of exerting a linear force in response to an electrical current. The motor should be  
10 capable of miniaturization to fit inside an implantable device and operate under battery power such that the battery life lasts for years.

This invention has been described and specific examples of the invention have been portrayed. The use of those specific examples is not intended to limit the invention in any way. Additionally, to the extent that there are variations of  
15 the invention which are within the spirit of the disclosure and yet are equivalent to the inventions found in the claims, it is our intent that those claims cover those variations as well.

WE CLAIM AS OUR INVENTION:

1. A heart support structure, comprising:
  - at least one peripheral link configured for attachment to at least one region of viable heart tissue; and
  - 5 at least one support link having a proximal end and a distal end, the proximal end configured for attachment to the peripheral link, the support link extendable to and configured for attachment to a second region of less viable or non-viable heart tissue.
- 10 2. The heart support structure of claim 1 wherein the distal end of the support link is configured for attachment to the second region of the less viable or non-viable heart tissue.
3. The heart support structure of claim 1 wherein the support link is  
15 configured for attachment to the second region proximal to the distal end.
4. The heart support structure of claim 3 wherein the support link distal end is configured for attachment to a second peripheral link.
- 20 5. The heart support structure of claim 1 further comprising:
  - a plurality of additional peripheral links, each of said plurality of said peripheral links disposable on a plurality of additional regions of the viable heart tissue such that, the plurality of peripheral links substantially surround the less viable or non-viable heart tissue; and
  - 25 a plurality of additional support links, each of said plurality of additional support links being configured for attachment to (a) the plurality of additional peripheral links and (b) the second region.

6. The heart support structure of claim 1 further comprising:  
a plurality of additional peripheral links, each of said plurality of said  
peripheral links disposable on a plurality of additional regions of the viable heart  
5 tissue; and

a plurality of additional support links, each of said plurality of said support  
links being configured for attachment to (a) the plurality of additional peripheral  
links and (b) the second region, the support links being further interconnected.

10 7. The heart support structure of claim 1 wherein the support link  
comprises a plurality of turns, each of said plurality of turns defining a constant  
angle therebetween.

8. The heart support structure of claim 1 wherein the support link  
15 comprises a plurality of support nodes wherein a distance between adjacent of  
each said plurality of support nodes is constant.

9. The heart support structure of claim 1 wherein the support link is  
tapered.  
20

10. The heart support structure of claim 1 wherein the support structure  
is comprised of a material selected from the group consisting of superelastic  
alloys, stainless steel, superelastic polymers, and any combinations thereof.

25 11. The heart support structure of claim 10 wherein the superelastic  
alloy comprises nickel-titanium.

12. The heart support structure of claim 1 further comprising a coating covering at least a portion of the support structure.

13. The heart support structure of claim 12 wherein the coating  
5 comprises a material selected from the group consisting of thermoplastics, thermoset plastics, silicone, parylene, heparin, thromboresistance substances, antiproliferative substances, platinum, gold, tantalum, tin, tin-indium, zirconium, zirconium alloys, zirconium oxide, zirconium nitrate, phosphatidyl-choline, and pyrolytic carbon.

10

14. The heart support structure of claim 1 further comprising a radiation source.

15. The heart support structure of claim 1 wherein the heart support  
15 structure is attachable to the viable heart tissue and the less viable or non-viable heart tissue by a bonding method selected from the group consisting of the use of adhesives, coagulation, and mechanical securing mechanisms.

16. The heart support structure of claim 15 wherein the bonding  
20 method comprises the use mechanical securing mechanisms and wherein the mechanical securing mechanisms are selected from the group consisting of anchors, sutures, flaps, implantable clips, and staples.

17. The heart support structure of claim 16 wherein the mechanical  
25 securing mechanisms are each connected to an electrosurgical generator capable of transmitting radio frequency energy into the viable and less viable or non-viable heart tissue.



18. The heart support structure of claim 1 further comprising a tissue interface disposed between the support structure and the viable and the less viable or non-viable heart tissue.

5

19. The heart support structure of claim 18 wherein the tissue interface comprises a material selected from the group consisting of harvested biological material and synthetic graft material.

10

20. The heart support structure of claim 19 wherein the synthetic graft material further comprises a biologically inert coating selected from the group consisting of parylene, heparin solutions, hydrophilic solutions, thromboresistance substances, antiproliferative substances, and endothelial cells.

15

21. The heart support structure of claim 1 further comprising an electromagnetic assist device configured to induce a magnetic field causing an expansion or contraction of the structure.

20

22. A method of transferring energy from viable heart tissue to less viable or non-viable heart tissue by utilizing a natural motion of a heart, comprising:

a) positioning a support structure over the viable and the less viable or non-viable heart tissue; and

b) attaching the support structure to the viable heart tissue and to the less viable or non-viable heart tissue such that the support structure exerts a force against the less viable or non-viable heart tissue in response to the motion of the heart.

25

23. The method of claim 22 wherein the support structure comprises at least one peripheral link and at least one support link.

24. The method of claim 23 further comprising inducing a magnetic  
5 field such that the support structure contracts or expands.

25. The method of claim 24 further comprising synchronizing the contraction or expansion with the natural motion of the heart.

10 26. A device for transferring energy from viable tissue to less viable or non-viable tissue, comprising:

a support structure secured at a plurality of attachment points to (a) said less viable or non-viable tissue in a central region and (b) said viable tissue extending around said less viable or non-viable tissue.

15

27. The device of claim 26 wherein said support structure further comprises a plurality of support links, each support link attached at one end to one of a plurality of peripheral links and at another end to selected of said plurality of attachment points, said attachment points located adjacent injured heart tissue.

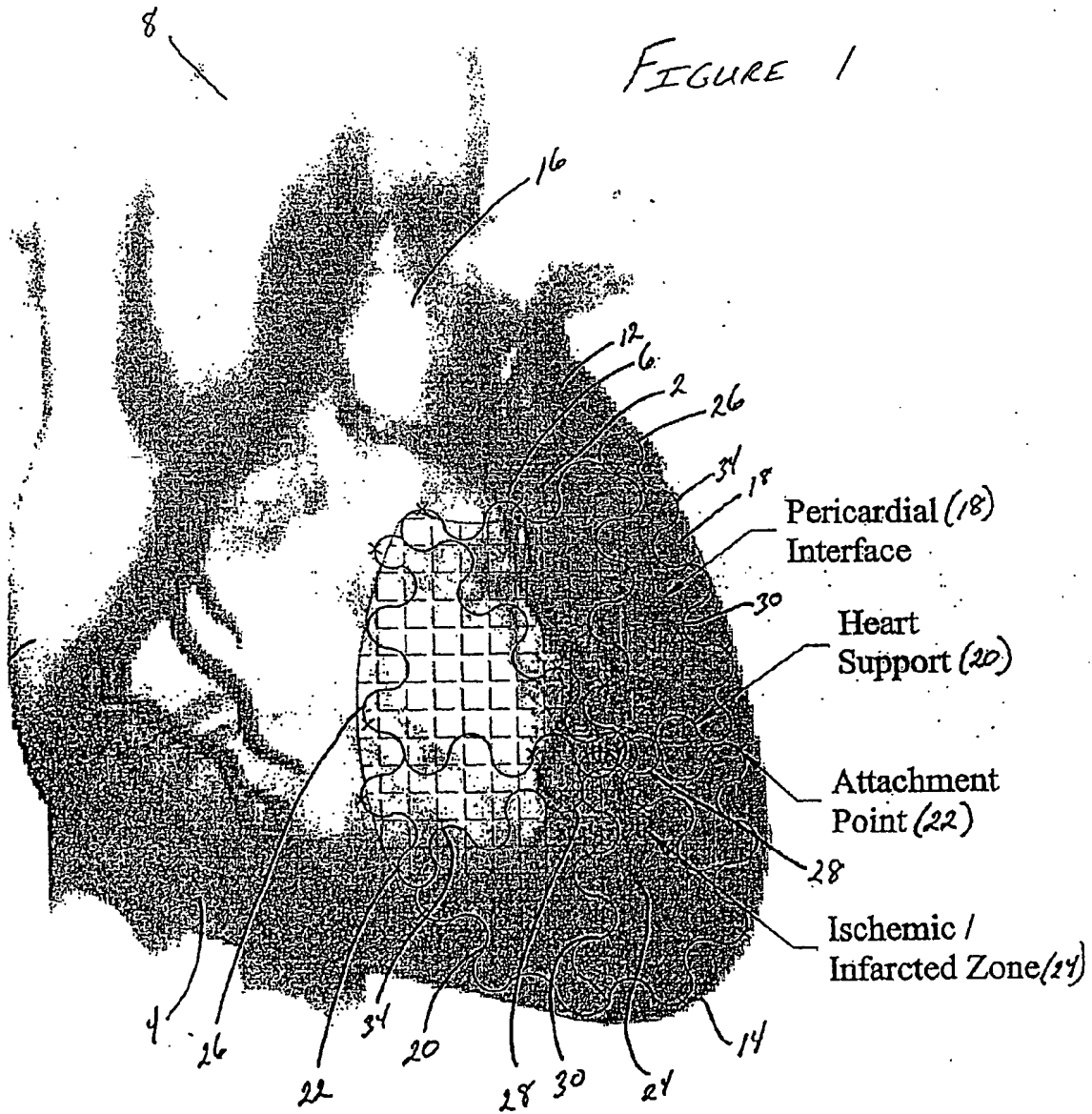
20

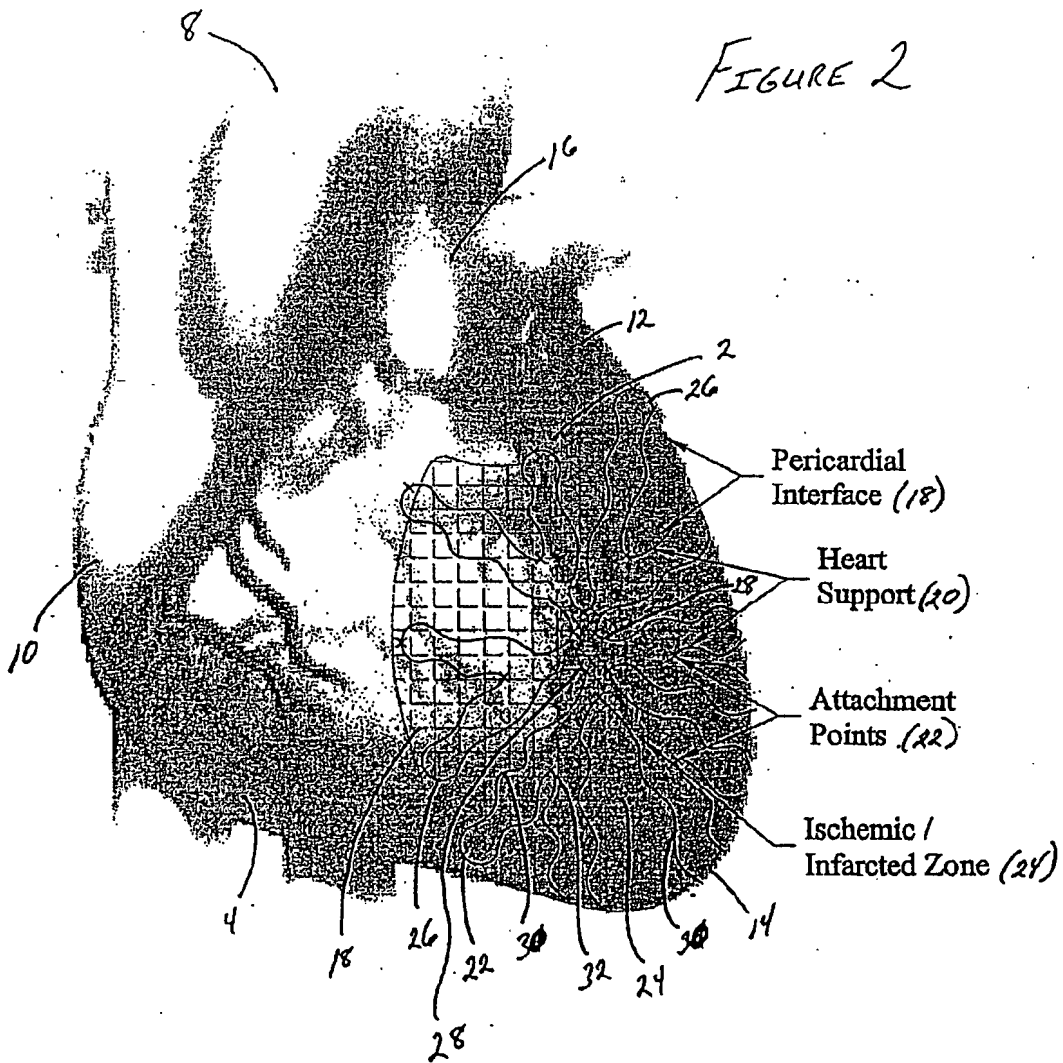
28. The device of claim 26 wherein the support structure has a generally conical shape.

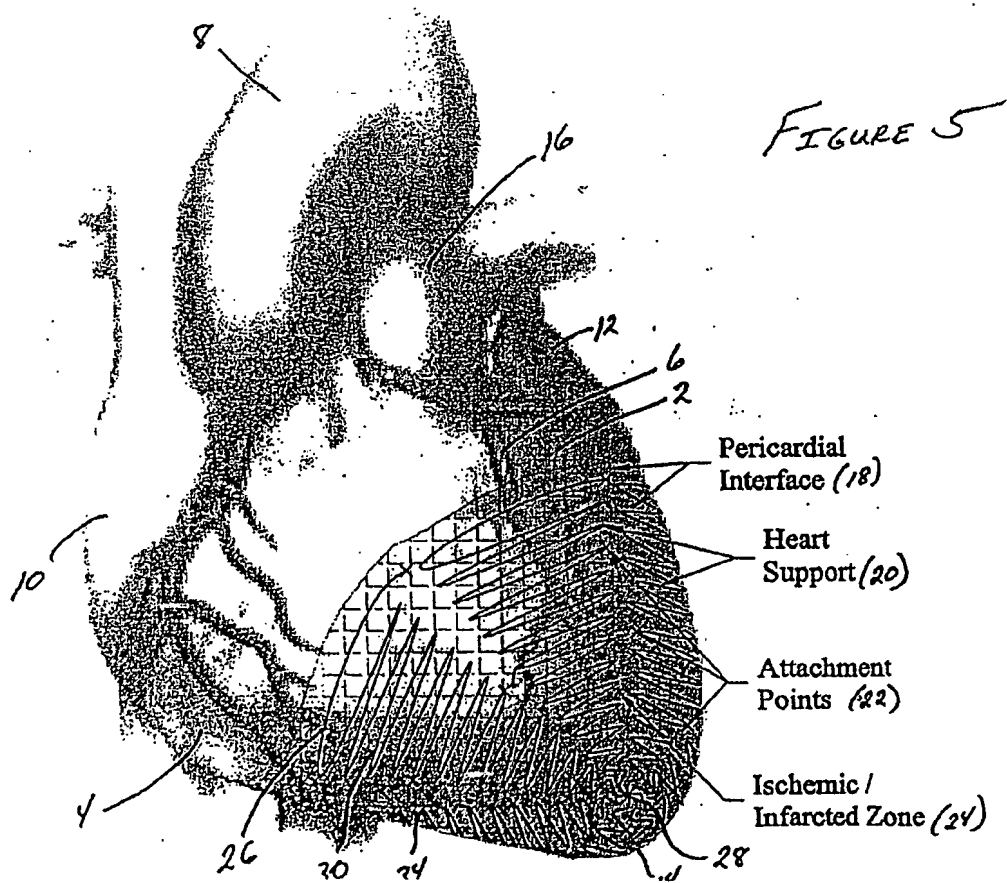
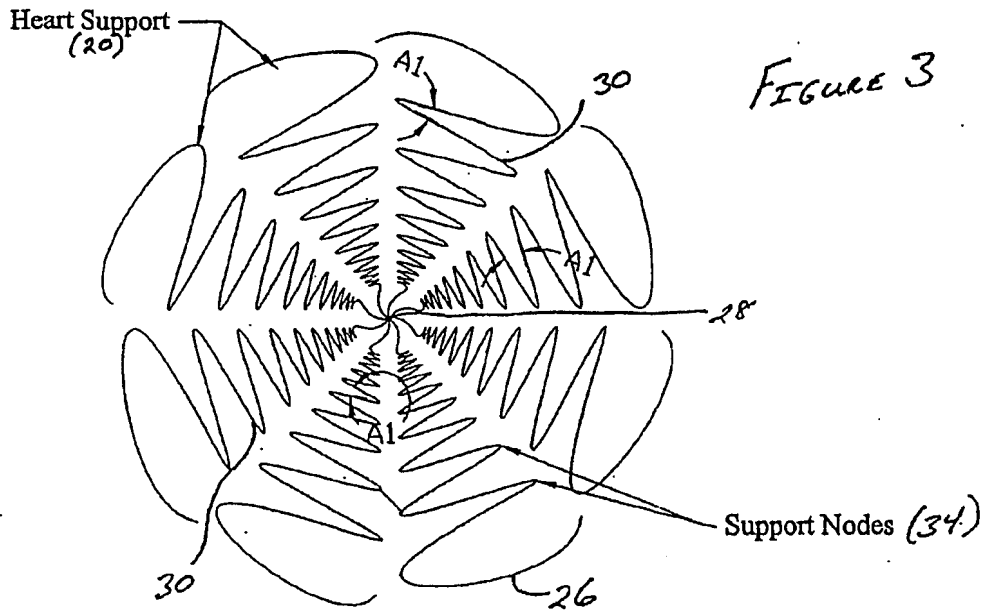
29. The device of claim 27 wherein the support structure has a  
25 generally planar shape.

30. The device of claim 26 additionally comprising a tissue interface disposed between (a) the support structure and (b) said viable and less viable or non-viable tissue.

5 31. The device of claim 27 wherein the central region comprises a region of multiple intersecting, interlocking, or adjacent support links.







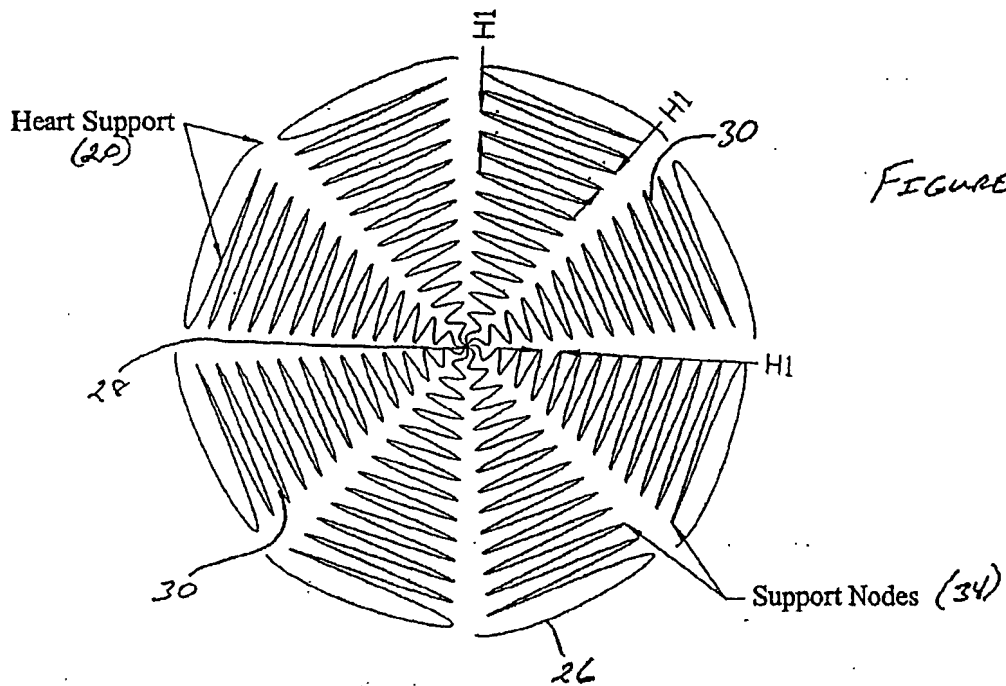


FIGURE 4

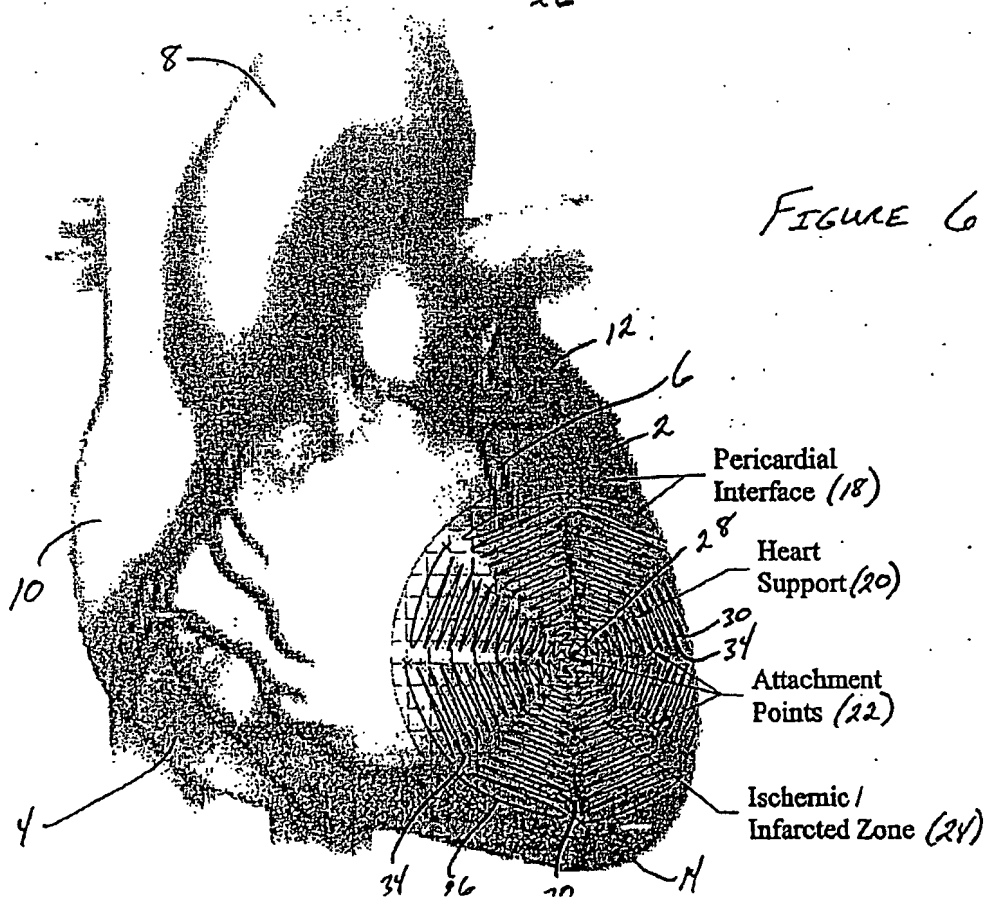


FIGURE 6

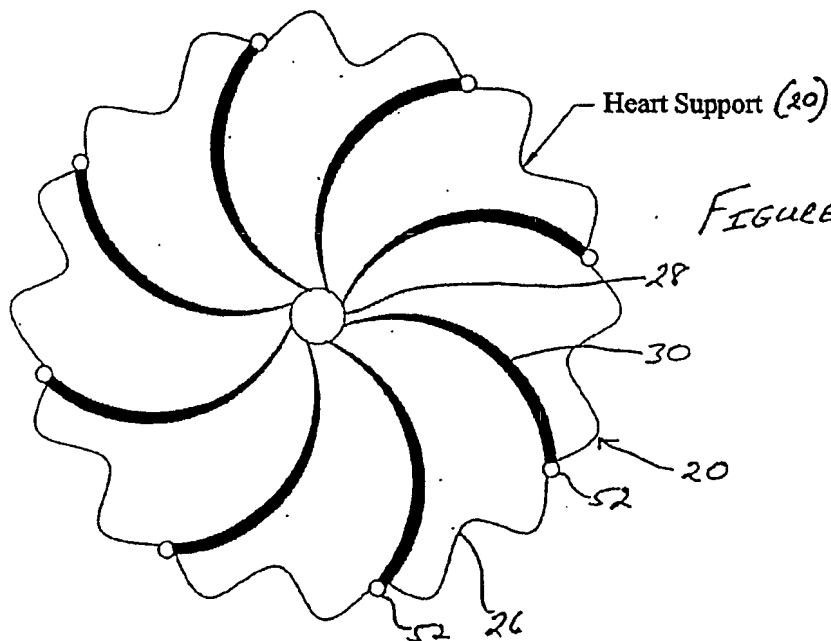


FIGURE 7

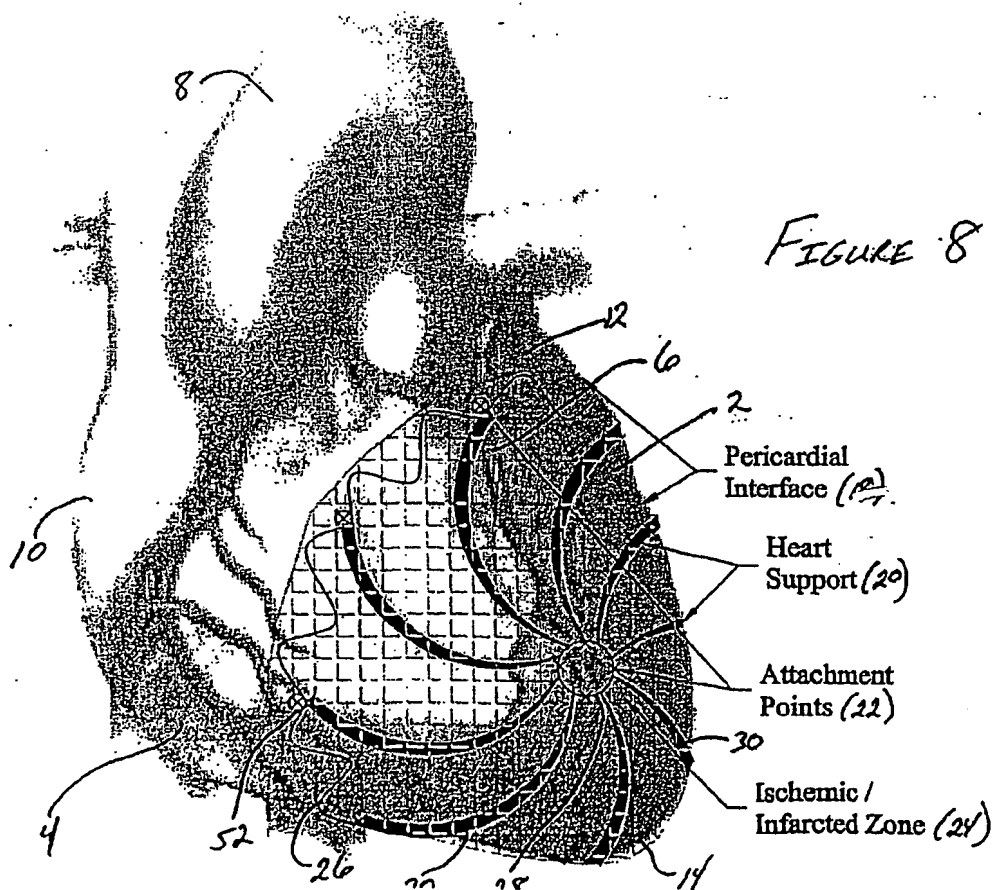


FIGURE 8



Figure 9b

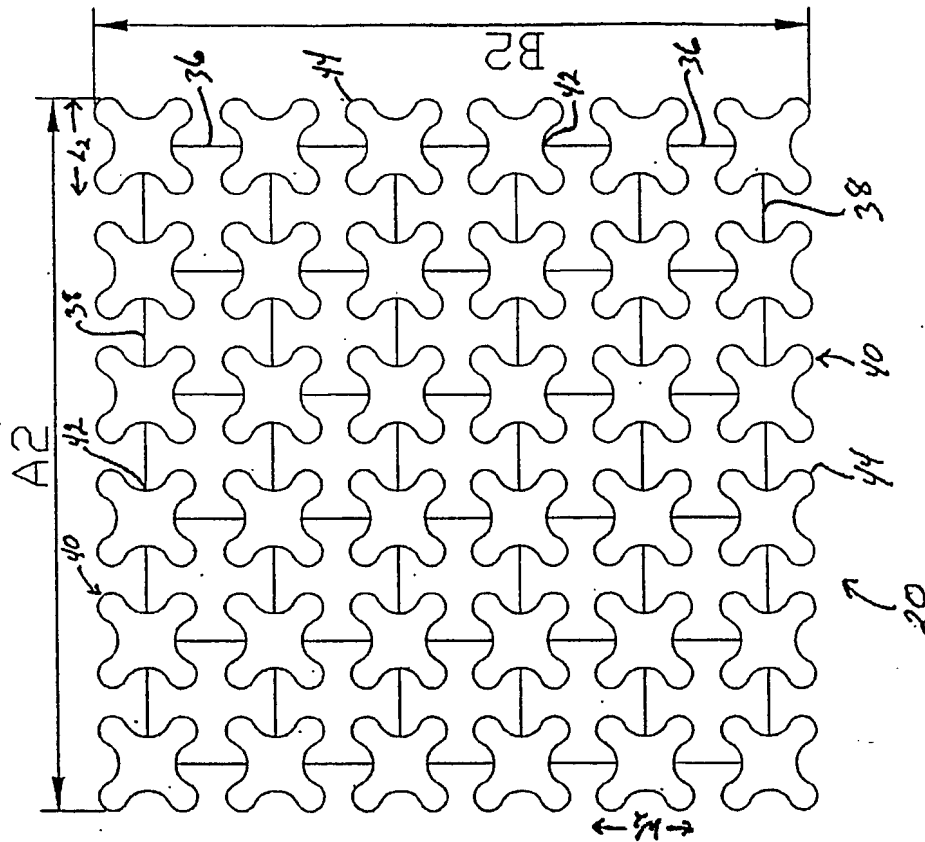
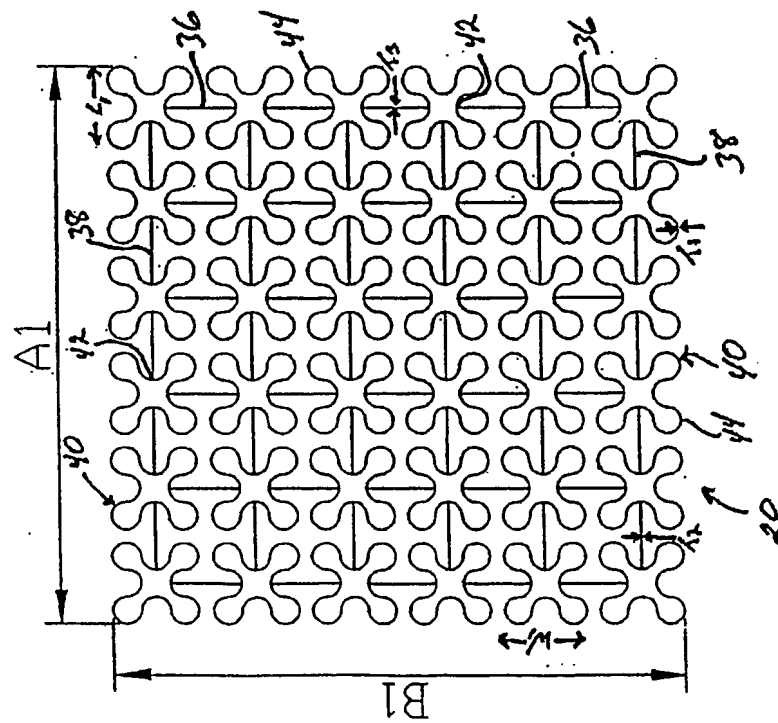


Figure 9a



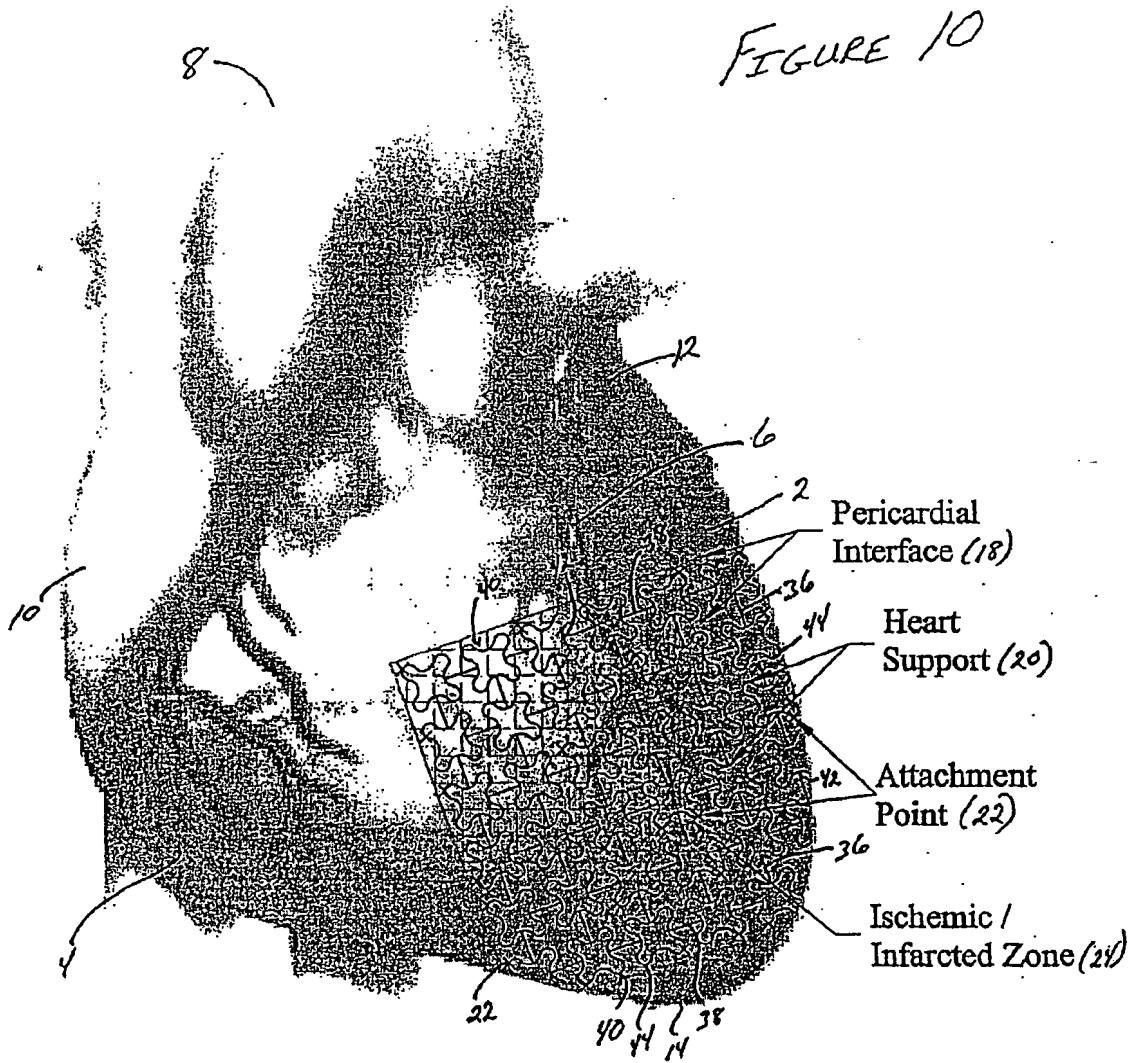
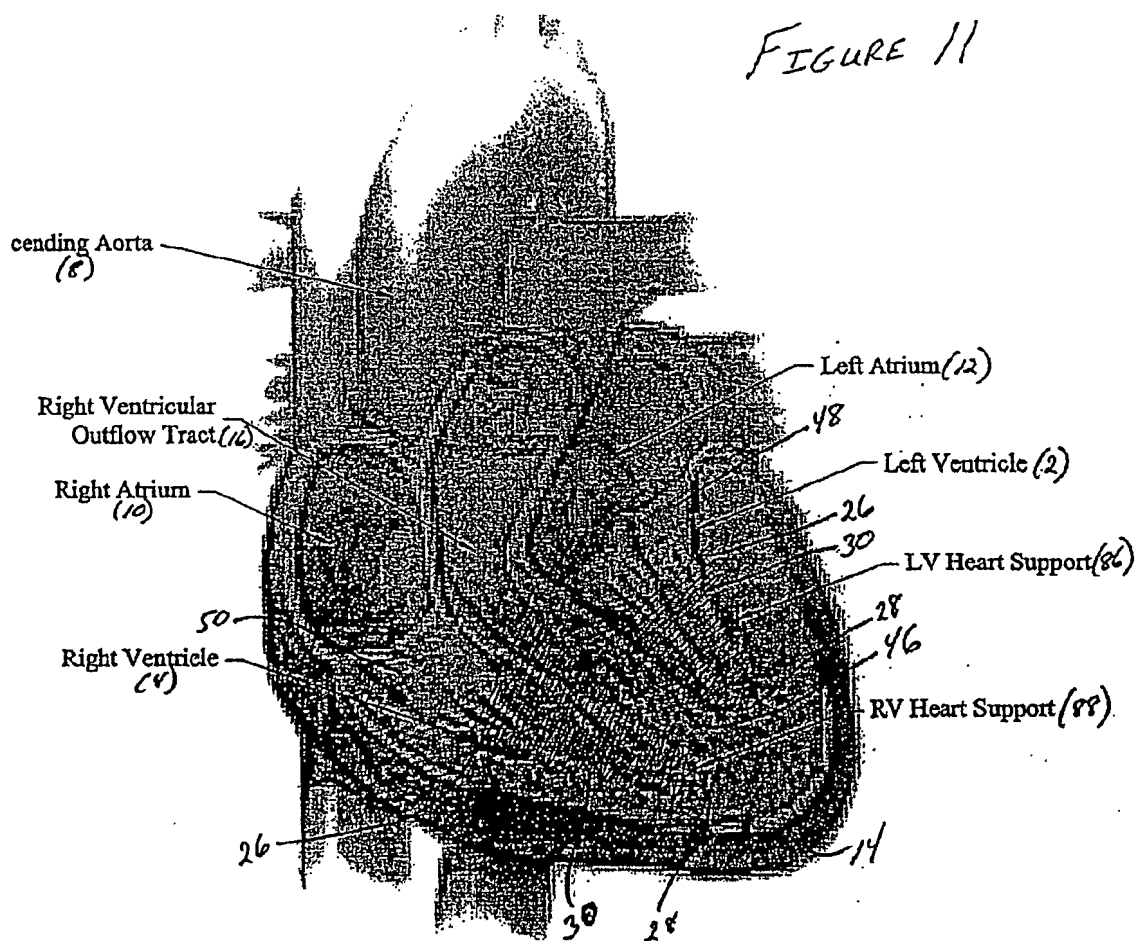


FIGURE 11



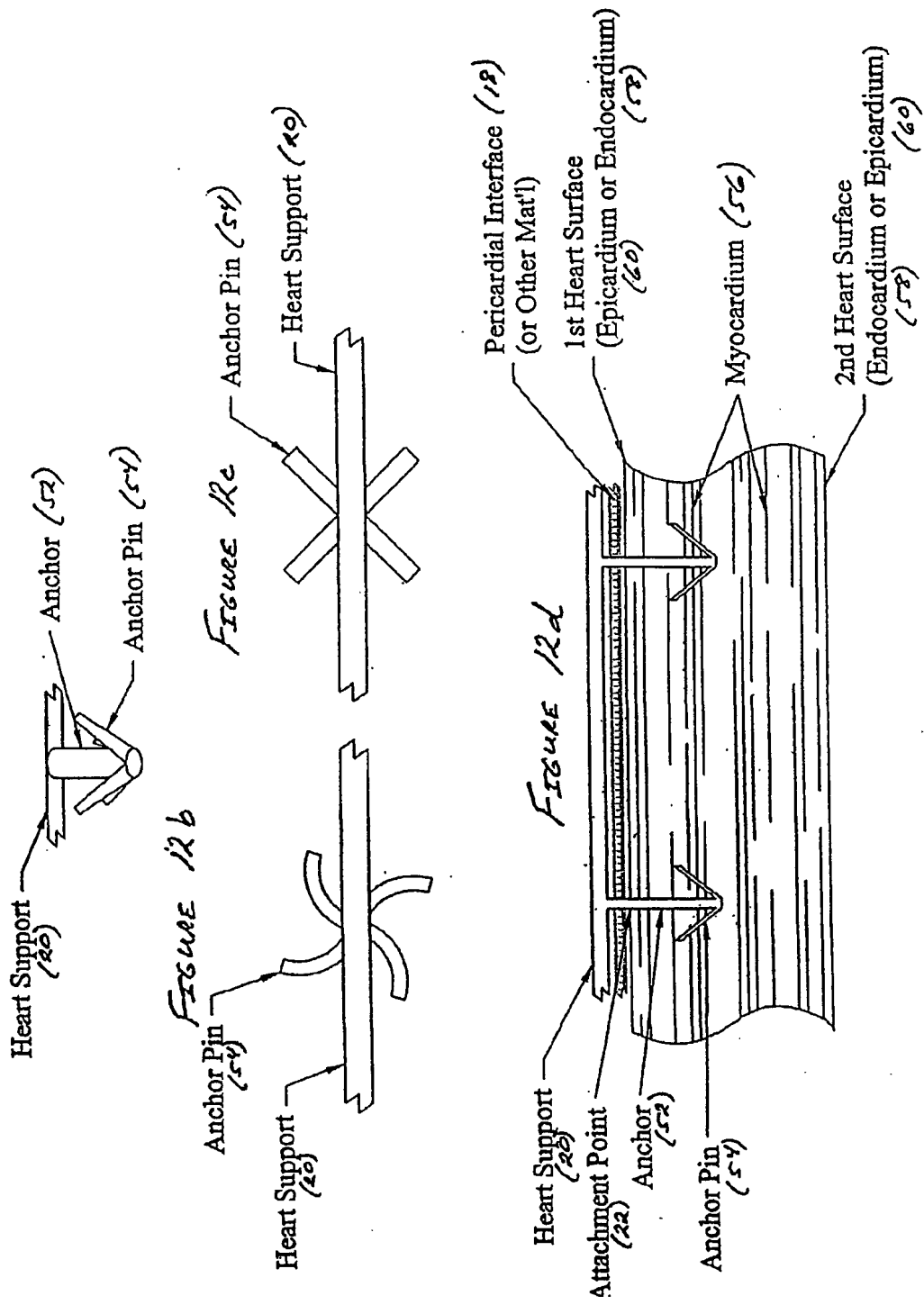


FIGURE 13a

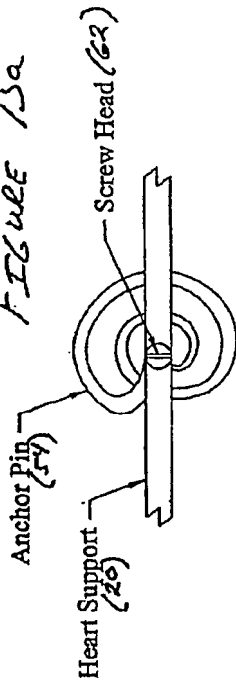


FIGURE 13b

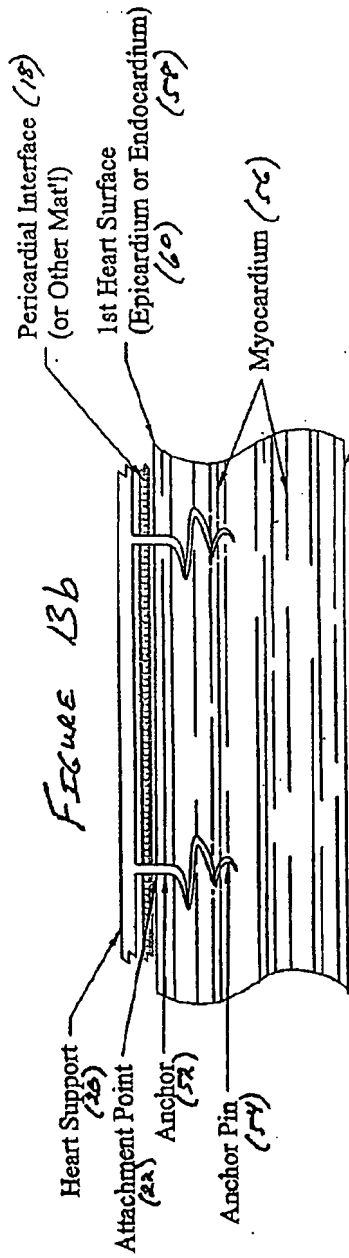


FIGURE 13c

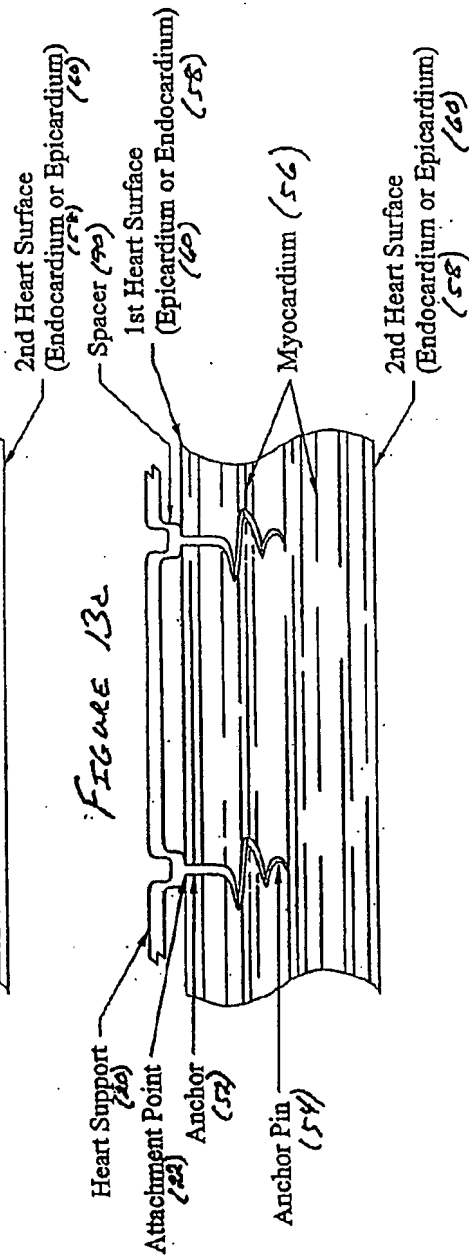


FIGURE 14a

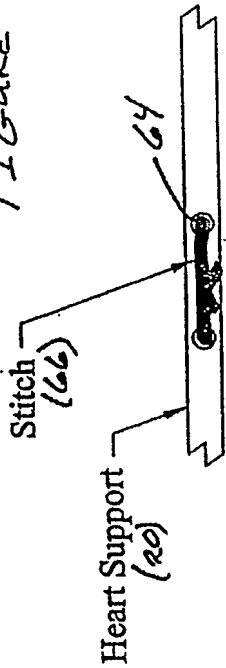


FIGURE 14b

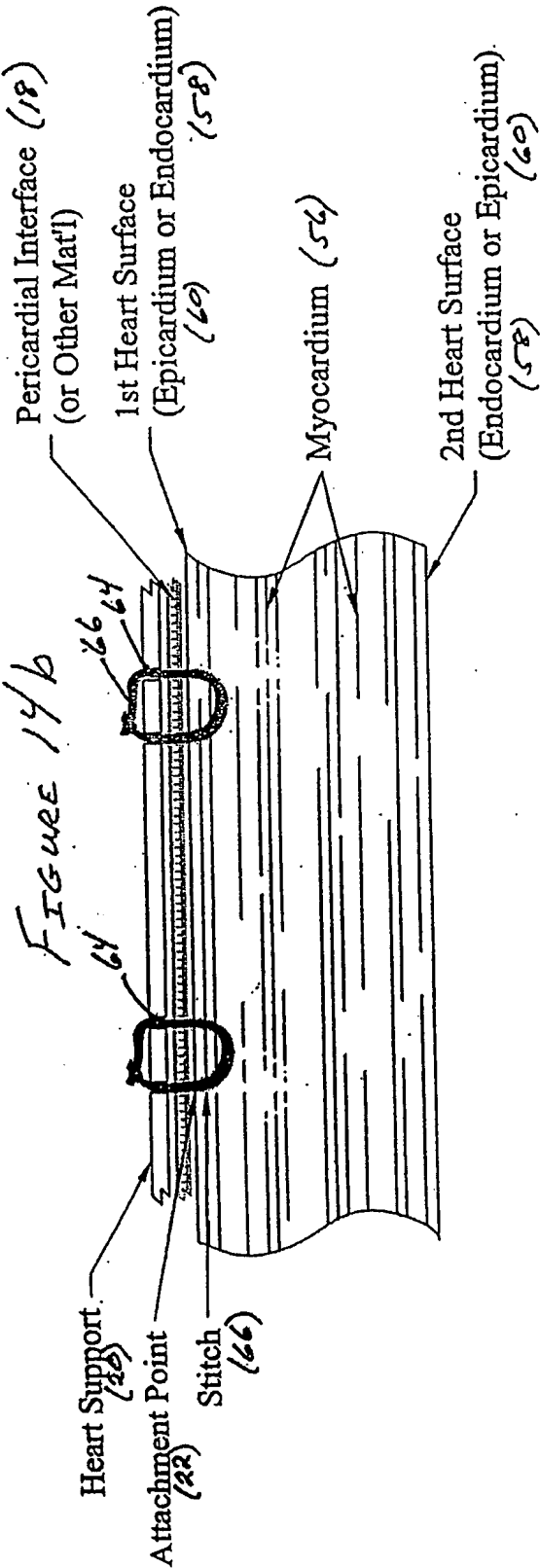


FIGURE 15a

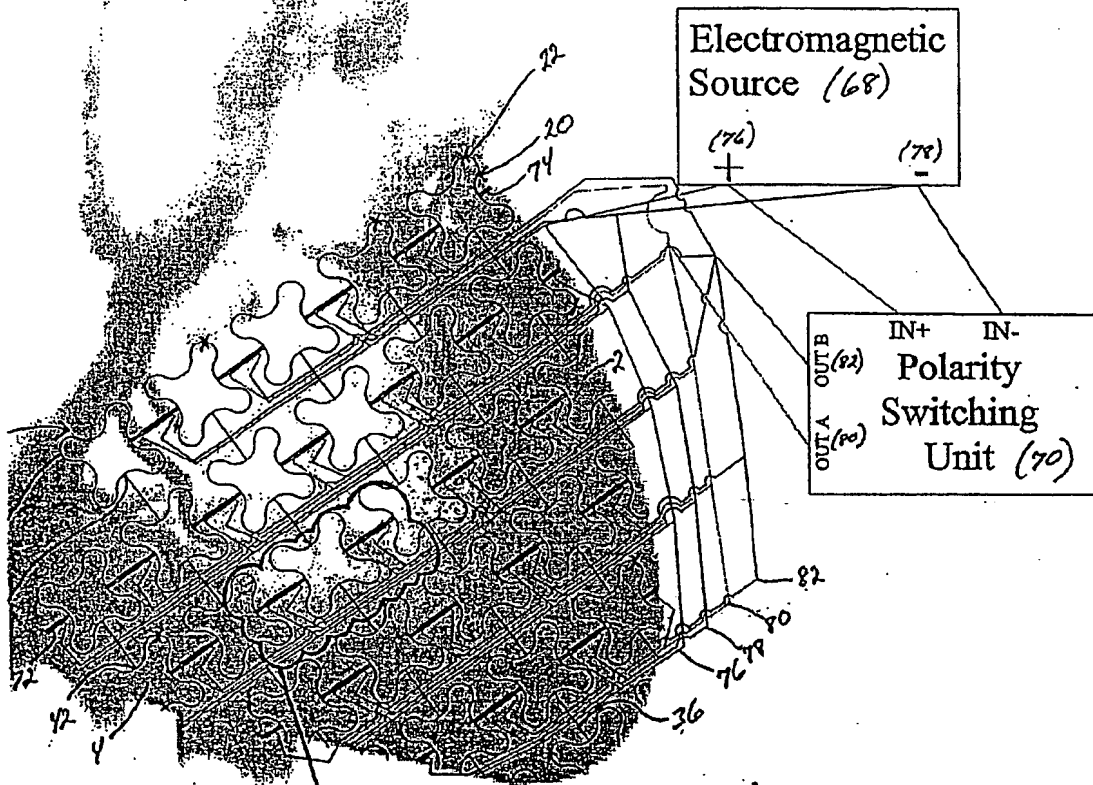


FIGURE 15b

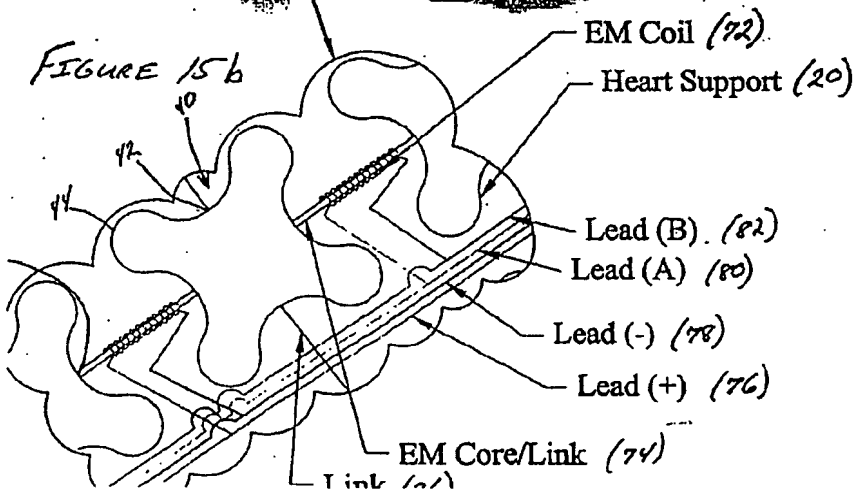


FIGURE 16a

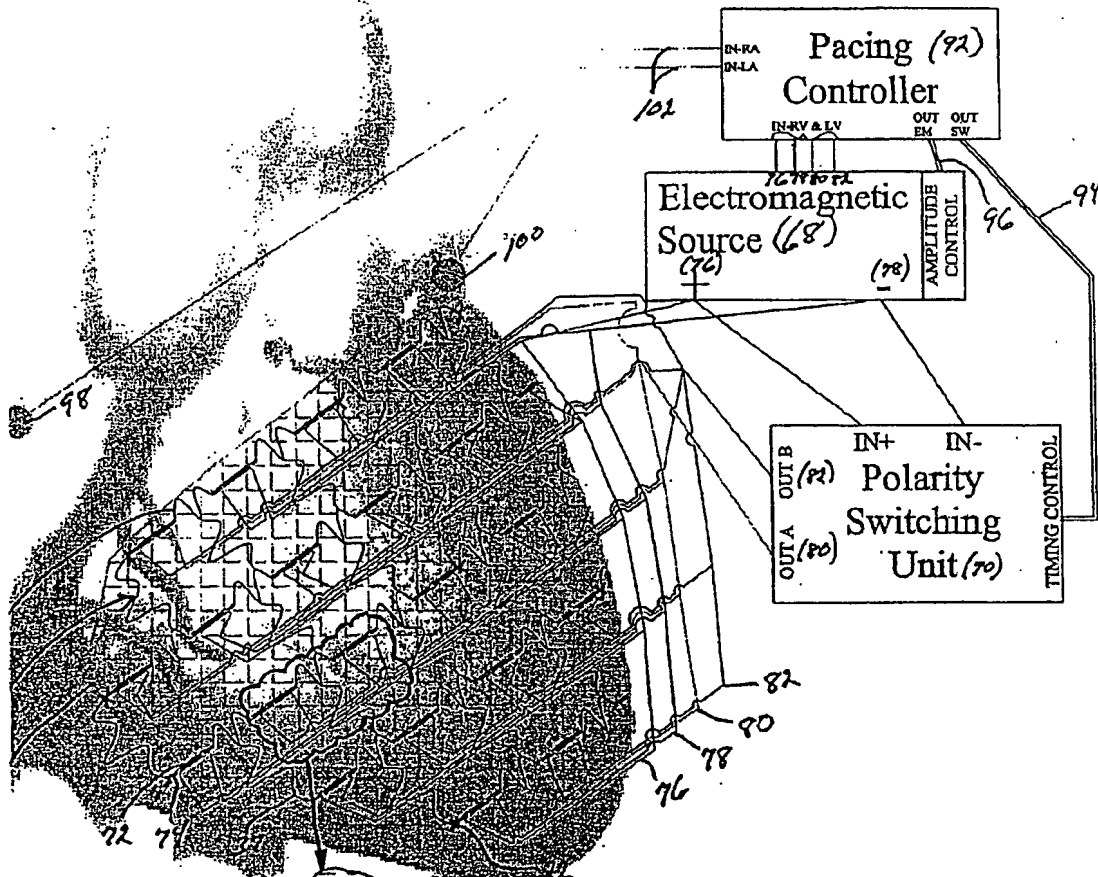
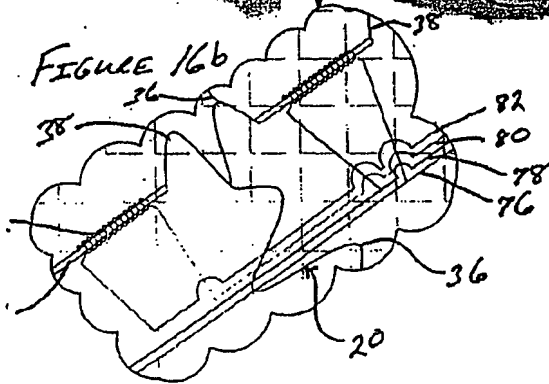


FIGURE 16b





# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 01/27492

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC 7 A61B17/00		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00 16700 A (SCHWEICH CYRIL J JR ;KEITH PETER T (US); KUSZ DAVID A (US); MORTIE) 30 March 2000 (2000-03-30) page 7, last paragraph -page 8, paragraph 2; figures 3,5	1,10,11, 15,16, 19,26,28
A	US 6 076 013 A (BURKHOFF DANIEL ET AL) 13 June 2000 (2000-06-13) column 4, line 22 -column 6, line 10; figures 1-5	1,14,26
A	US 5 713 954 A (KUNG ROBERT T V ET AL) 3 February 1998 (1998-02-03) claim 2; figure 2	1,14,26, 28
A	WO 99 55399 A (DENKER STEPHEN) 4 November 1999 (1999-11-04) the whole document	1,14,15, 21,26,28
-/-		
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents : *A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *&* document member of the same patent family		
Date of the actual completion of the international search 11 December 2001		Date of mailing of the international search report 19/12/2001
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016		Authorized officer Ducreau, F

## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 01/27492

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 621 617 A (SHARMA DEVENDRA N) 11 November 1986 (1986-11-11) column 4, line 4 - line 44; figure 1 -----	1,14,15, 21,26,28
A	DE 198 26 675 A (HAINDL HANS) 4 March 1999 (1999-03-04) abstract -----	1,26

## INTERNATIONAL SEARCH REPORT

Int: al Application No  
PCT/US 01/27492

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0016700	A	30-03-2000	US 6183411 B1 AU 5925199 A EP 1115335 A1 WO 0016700 A1	06-02-2001 10-04-2000 18-07-2001 30-03-2000
US 6076013	A	13-06-2000	NONE	
US 5713954	A	03-02-1998	US 6224540 B1 US 5800528 A	01-05-2001 01-09-1998
WO 9955399	A	04-11-1999	US 6099460 A AU 3570199 A EP 1075290 A2 WO 9955399 A2 US 6309341 B1	08-08-2000 16-11-1999 14-02-2001 04-11-1999 30-10-2001
US 4621617	A	11-11-1986	GB 2115287 A ,B	07-09-1983
DE 19826675	A	04-03-1999	DE 19826675 A1 DE 29824017 U1 WO 9858598 A1 EP 0991373 A1	04-03-1999 25-05-2000 30-12-1998 12-04-2000

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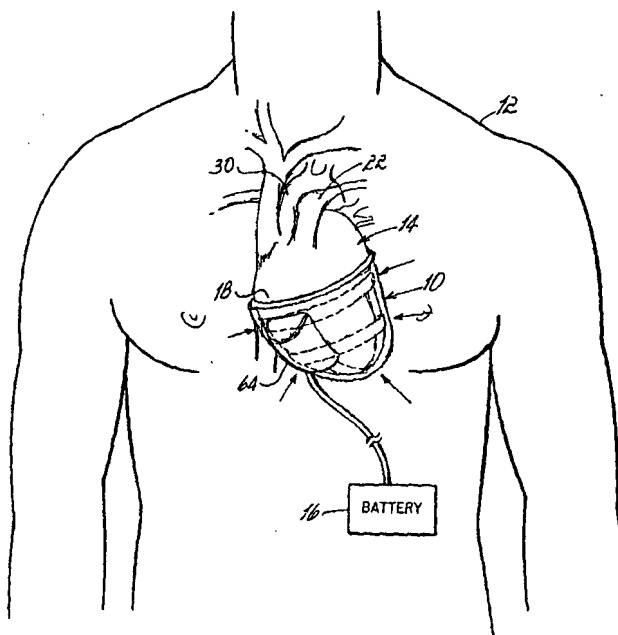
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(54) Title: **IMPLANTABLE HEART ASSIST DEVICES AND METHODS**



(57) Abstract: Heart support and assist devices (10) for supporting and assisting the pumping action of the heart (14). Various embodiments include mesh support devices (150), devices (10, 130) using straps, spiral-shaped devices (80), catheter-based devices (200) and related methods.

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## IMPLANTABLE HEART ASSIST DEVICES AND METHODS

### Field of the Invention

The present invention generally relates to devices used to physically support the heart and, alternatively, also actively assist the pumping action of the heart.

### 5 Background of the Invention

The treatment of heart failure over the long term is a difficult problem. At the same time, weak cardiac muscle function is becoming an increasing problem. Patients are surviving longer and more patients are surviving myocardial infarcts leading to a large pool of patients who are  
10 inadequately served by current medical practice. Drug treatment to increase the strength of myocardial contraction has been unsuccessful over the long term. Recently, biventricular pacing (rather than the usual univentricular pacing) has been tried and this offers some promise in selected patients but is unlikely to solve the problem.

15 Devices will therefore remain the mainstay of treatment for terminal heart failure. Conventional methods have been unable to inject adequate energy into the cardiovascular system. Past attempts with the Jarvic heart or other replacement systems have met with problems such as failure due to thromboembolism. The patient is typically connected to a  
20 bulky internal or external controller and power supply for the heart

replacement system. The inside of the artificial heart exposes a large artificial surface area to the flow of blood and clots develop as a result. These clots eventually break off and lodge in the brain leading to strokes or resulting in ischemic injury to other body organs. It has also been

5 postulated that long-term exposure of blood to large artificial surfaces sets up a chronic inflammatory reaction which may predispose the patient to infection.

Currently, there are two major areas of development. A simplified system involves cannulation of the left ventricle or atrium with a

10 tube-like structure and pumping of blood from this source into the aorta. A blood propeller system is located within the tubing of this system. A drive system powers the pump. The drive system can be located outside the patient, or can be implanted within the patient. If implanted, energy may be transmitted by induction coils from outside the body to the device. This

15 device requires considerable residual cardiac function to operate. The heart must beat adequately to perform some function and usually only the left ventricle is supported by the device. Thus, right ventricular function must be adequate for survival.

The second and more complex pump is a totally implantable

20 heart. The patient's heart is entirely removed or both ventricles are cannulated and artificial left and right ventricles are attached by a surgeon. The patient has a large surface exposed to the flow of blood as the blood comes in contact with the artificial ventricles, the connection tubes and the

valves. Blood clotting, hemolysis and degradation of blood become problems in this situation.

For an entire generation, attempts have been made to create a heart assist device which leaves the native heart in place and squeezes the native heart. The blood is thus exposed only to the patient's natural tissue. Clotting on natural tissue is extremely rare. Pneumatically and electrically driven devices have been evaluated, but these devices have not reached clinical application. These devices have wrapped around the entire heart and squeezed both the left and right ventricles. Unfortunately, this does not mimic the way the heart contracts.

U.S. Patent No. 4,925,443 illustrates a heart assist device including a tension band which is surgically placed within an interventricular muscle wall in order to compensate for weakness of the interventricular muscle wall or septum. An operating mechanism then opens and closes a pair of pressure plates to compress the left ventricle. The drawback to this device, however, is that the interventricular wall or septum experiences significant trauma due to the surgical implantation of the band within the wall or septum itself. Especially in cases in which the interventricular wall is already weakened, such trauma could severely damage the heart.

Another proposed device is disclosed in U.S. Patent No. 5,119,804. With this device, the heart is placed within a cup having a vacuum source connected to hold the cup in position around the heart and having a pulsed pressure system to alternately apply relatively high positive and negative pressures to provide systolic and diastolic effects on the heart.

This system, however, squeezes the entire heart muscle at one time and will tend to cause weaker portions of the heart to bulge outward while stronger portions of the heart muscle retain a normal shape. Therefore, the contraction applied to the heart muscle is not a natural one, but one that is  
5 dictated by the particular heart problems of the patient.

Another ventricular assist device is disclosed in U.S. Patent No. 4,685,446. This device utilizes an inflatable balloon secured to the end of a catheter and inserted into the left ventricle. The balloon is inflated during left ventricular systole and then deflated in a repeating manner.  
10 Unfortunately, this device will also tend to cause weakened portions of the heart muscle to bulge around the left ventricle rather than causing the intended function of expelling blood from the ventricle. Thus, the ejection fraction of blood can be deficient with this device as well.

Despite the intuitively attractive nature of heart assist devices,  
15 no device has ever been clinically proven. Attention to some physiologic details will make the difference. The left ventricle is a thick-walled structure which propels blood into the systemic circulation at high pressure. The left ventricle is shaped as a truncated cone. During systole (contraction) this cone shortens along its length and narrows around its  
20 circumference. By this narrowing and shortening action, the internal volume of the left ventricular cavity decreases and blood is expelled. In a healthy heart, 60% to 70% of the blood volume (that is, the ejection fraction) is expelled on each beat. As the heart fails, the cavity enlarges, the heart wall thins and progressively smaller fractions of blood are expelled.



on each beat. In other words, the heart shortens and narrows much less during each beat.

The right ventricle has been described as a bellows pump. It wraps around and attaches to the circumference of the outside of the left ventricular wall. The outside wall of the right ventricle is considerably thinner than the wall of the left ventricle and also contracts against a lower pressure. The energy consumption of the right ventricle is therefore much lower than that of the left ventricle. The right ventricle expels blood when the muscle shortens and reduces the diameter of the crescent shaped cavity which is located between the outside wall the interventricular wall or septum shared with the left ventricle.

It is not surprising that merely squeezing the left and right ventricles with a device wrapped around both ventricles has not been successful. With previous devices, the left ventricle does not shorten from base to apex. There is also limited short axis shortening because the device does not squeeze the left ventricle in isolation, but with the right ventricle. To be effective the left ventricle requires more controlled compression. Generally, blood must be expelled from the ventricle in a more controlled and complete manner.

## 20 Summary of the Invention

The present invention is generally directed toward heart support and assist devices including fully passive restraints, combinations of passive and active devices and fully active devices for assisting with

heart contractions. Passive restraints generally include an external support member, which may be a strap, web or mesh, sheathing or other member configured to extend around the outside of the heart coupled with an internal support member extending within at least one of the ventricles and  
5 against one side of the interventricular septum. This type of passive restraining system can assist the heart muscle by supporting those portions of the muscle necessary to produce efficient contractions either naturally or with another active assist device. This support is provided in a manner that minimizes trauma to the heart muscle. Additional internal tensile members,  
10 such as cables, may be connected to the external tensile member or members longitudinally and/or transversely through one or both ventricles. These cables will assist with long axis and short axis shortening of the heart muscle during each contraction.

Combinations of passive and active devices may include, for  
15 example, external support members, in the form of straps, sheaths, wraps, mesh elements or webs, etc., combined with a blood pump connected for fluid communication directly with the left ventricle, right ventricle or both. Alternatively, a fluid inflatable bladder may be placed between the external tensile member and the outside surface of the heart to provide compression  
20 to one or both of the ventricles to assist in pumping blood through the heart. Finally, an active contraction device may integrate an external tensile member system with a powered actuator device to provide cyclical compression of the heart muscle through a pulling action on the tensile member or members.

In another aspect, the invention is directed to a heart assist device generally including a plurality of flexible tensile members adapted to be wrapped circumferentially about the heart of a patient. At least one tensile member is configured to extend around the left ventricle and a  
5 second tensile member is configured to extend around the right ventricle. A support member is configured to be received within the right ventricle against the interventricular septum and coupled to at least one of the first and second tensile members. This support member may be a portion of at least one of the tensile members or may be a separate member connected  
10 to at least one of the tensile members. At least one powered actuator may be operatively connected with the first and second tensile members and operates to pull the tensile members respectively against the left and right ventricles to expel blood therefrom.

More preferably, the heart assist device includes a plurality of  
15 tensile members configured to extend around the left ventricle and a plurality of tensile members configured to extend around the right ventricle. Each tensile member is secured at least indirectly to the support member. The support member is preferably a plate covered with a biocompatible material for inhibiting blood clotting. The actuator pulls the tensile members  
20 extending around the left ventricle against the outside surfaces of the heart and pulls the support member or plate against the interventricular septum in an opposing direction. The tensile members extending around the right ventricle are pulled against the left ventricle in an independent fashion.

One preferred embodiment of the invention may include a plurality of pulley members coupled with the tensile members and operating to allow a single powered actuator, such as an electric or pneumatic actuator, to pull multiple tensile members. Alternatively, multiple powered  
5 actuators may be used to independently pull the various tensile members. The tensile members, pulleys and other actuating structure may be contained in a suitable jacket or sheath positioned around the heart.

In accordance with another aspect of the invention, at least one internal tensile member is provided and configured to be connected  
10 lengthwise within the left ventricle between the mitral valve of the heart and the apex of the left ventricle. The internal tensile member inhibits lengthening of the ventricle when the powered actuator or actuators pull the tensile members to compress the left and right ventricles. As further options, transverse, internal tensile members may be connected within the  
15 left ventricle between the outside wall thereof and the interventricular septum to control widthwise expansion. Also, one or more internal tensile members may be utilized in the right ventricle for similar purposes.

As additional aspects of the invention, the tensile members may be contained in sleeves to prevent cutting of the heart by the tensile  
20 members during use. Also, a plurality of coronary obstruction preventing members may be used between the tensile members and the coronary arteries on the outside of the heart for preventing the coronary arteries from being compressed and obstructed by the tensile members.

The present invention also generally contemplates methods for assisting the pumping action of the heart. In a preferred embodiment, the method includes inserting an anchor member within the right ventricle and against the interventricular septum; encircling the outside of the right and  
5 left ventricles with respective tensile members; coupling the tensile members with the anchor member; and compressing the right and left ventricles by pulling the tensile members against the outside of the heart. Other methods will be apparent to those of ordinary skill based on a full review of this disclosure.

10 In various aspects of the invention, a basic device for assisting a heart may comprise a plurality of flexible, external tensile members adapted to be wrapped circumferentially around the heart of a patient. Preferably, this includes at least a first external tensile member configured to extend around the left ventricle and a second external tensile member  
15 configured to extend around the right ventricle. In accordance with the invention, an internal support member is configured to be received within at least one of the left and right ventricles and against the interventricular septum. This support member is coupled either directly or indirectly to at least one of the first and second external tensile members. The internal  
20 support member may comprise a portion of one or more of the external tensile members or may be a separate member, such as a plate, coupled with the external tensile members. The external tensile members are preferably flat straps or other similar structures that will not harm the outside of the patient's heart, and may be formed from any biocompatible

material. In various embodiments, the support members may be implanted either partially or completely through one or more catheters.

In another embodiment of the invention, at least one of the first and second external tensile members may be configured generally in a spiral shape to facilitate the application of compression to the heart. In this embodiment, for example, one or more coils of the spiral may extend into one of the ventricles of the heart and bear against one side of the interventricular septum to form a support member as described above. An actuator is used to draw the spiral-shaped external tensile member into a tighter, coiled shape to actively compress or passively support one or both ventricles of the heart.

In another embodiment of the invention, the first and second external tensile members are configured as first and second halves of a cup. The cup is configured to envelop the patient's heart and comprises first and second shells with at least a first bladder configured for disposition between one of the shells and an outside surface of the heart. As with the other embodiments, one or more support members extend between opposite sides of the cup and within one or both ventricles of the heart to bear against the interventricular septum. A pump is provided for selectively inflating and deflating the bladder to apply compression to at least one of the left and right ventricles. In the preferred embodiment, a bladder is connected within each of the shells associated with the cup for compressing both of the ventricles. The support member or members are connected at a position generally between the first and second halves of

the cup such as by being retained in place by the same connectors used to affix each half of the cup together. The cup may be formed in one, two or more pieces and, again, is formed from any suitable biocompatible material or materials as with all of the implantable components of each embodiment.

5                Various objectives, features and advantages of the invention will become more readily apparent to those of ordinary skill in the art upon review of the following detailed description taken in conjunction with the the accompanying drawings.

#### **Brief Description of the Drawings**

10                Figure 1 is a perspective view showing one embodiment of the invention in an illustrative manner coupled to a patient's heart;

                  Figure 2 is a partially fragmented perspective view showing the heart assist device of Figure 1 coupled to the patient's heart;

                  Figure 3 is a cross sectional view taken generally along line  
15    3-3 of Figure 2;

                  Figure 3A is a cross sectional view similar to Fig. 3, but illustrating optional inflatable bladders for providing a pump assist to the heart;

                  Figure 4 is perspective view illustrating an embodiment with a  
20    single powered actuator for operating the heart assist device through the use of pulleys;

                  Figure 5 is a perspective view similar to Figure 4, but showing independent powered actuators;

Figure 6 is a perspective view of another alternative assist device comprising a spiral-shaped external tensile member;

Figure 7 is an exploded perspective view illustrating another alternative heart assist device comprised of a split cup and inflatable  
5 bladder system;

Figure 8 is a perspective view of another alternative heart assist device used to directly pump blood into one or more heart chambers;

Figure 9 is a fragmented perspective view of the heart with another embodiment of a passive heart support device implanted around  
10 the left ventricle;

Figure 10 is a perspective view of a passive heart support device similar to Figure 9 but having alternative internal support members;

Figure 11 is a transverse, cross sectional view of a heart with another alternative passive support device;

Figure 12 is a cross sectional view showing an initial step of  
15 implanting a catheter-implanted heart support device;

Figure 12A is a fragmented perspective view showing one embodiment of a catheter-implanted heart support device;

Figure 13A is a schematic, cross sectional view of the heart  
20 during a later step of implanting the catheter-implanted support device;

Figure 13B is a cross sectional view similar to Figure 13A, but illustrating the fully implanted, catheter-implanted passive support device;



Figure 14A is a transverse, cross sectional view of a heart schematically illustrating another catheter-based implantation method of a passive support device;

Figure 14B is a cross sectional view similar to Figure 14A, but  
5 illustrating a later point in the implantation procedure;

Figure 14C is a cross sectional view similar to Figures 14A and 14B, but illustrating the fully implanted support device;

Figure 15 is a partially sectioned, perspective view of a heart with another alternative passive support device affixed around the left  
10 ventricle;

Figure 16 is a schematic, perspective view showing the heart in cross-section and another alternative passive support device; and

Figure 17 is a schematic, cross sectional view of the heart shown in Figure 16 with the device fully implanted around the left ventricle.

## 15 **Detailed Description of the Preferred Embodiments**

Figure 1 illustrates a heart assist device 10 constructed in accordance with the invention and schematically illustrated implanted within a patient 12 in surrounding relation to the patient's heart 14. A power supply 16, such as an electric or pneumatic power supply, is  
20 operatively connected to heart assist device 10 for reasons to be discussed below. As generally shown in Figure 2, heart 14 has four chambers. The right atrium 18 receives blood flowing through veins in the patient's body. The right ventricle 20 pumps the blood to the lungs of the patient through

the pulmonary artery 22. The left atrium 24 receives oxygenated blood flowing back from the patient's lungs through the pulmonary vein and the left ventricle 28 pumps this blood out through the aorta 30 to the patient's body. The right and left ventricles 20, 28 compress simultaneously during  
5 this pumping action and, in a normal heart, anywhere between about 50% and 80% of the blood in these chambers will be expelled as described above. In a heart weakened, for example, due to heart attack or other conditions, the efficiency of the heart will be reduced and, therefore, heart assist device 10 will be used to increase the pumping action or expulsion of  
10 blood from the right and left ventricles 20, 28. An interventricular septum 32 separates the right and left ventricles 20, 28.

As further shown in Figures 2 and 3, device 10 preferably comprises a plurality of flexible tensile members 40a through 40f. In this embodiment, a flexible tensile member 40a is adapted to be wrapped  
15 circumferentially around left ventricle 28, as is another flexible tensile member 40b. A tensile member 40c may interconnect tensile members 40a and 40b as shown. A similar system is shown with tensile members 40d, 40e and 40f extending along the outside of right ventricle 20. Each of these tensile members is effectively connected to the other to form an  
20 integrated unit by connection to an internal support anchor member 42. In this embodiment, support member 42 comprises a plate surgically inserted into right ventricle 20 and bearing against interventricular septum 32. Plate 42 may comprise a plate of rigid or semi-rigid polymeric material or metallic material covered in a biocompatible material adapted to resist blood

clotting. Once plate 42 is implanted through a suitable incision into right ventricle 20, flexible tensile members 40a, 40b, 40d and 40e may be sutured thereto as shown in Figure 2. Alternatively, one of the pairs of tensile members may be secured to plate 42, while the other pair is secured  
5 to the first pair.

As shown in Figure 2, tensile members 40a through 40f may comprise flexible cables contained within a sheath or sleeve of biocompatible material. Internal flexible tensile members 44, 46, 48, 50 may be used to control the movements of the heart muscle as device 10 is  
10 used to assist with the pumping action as described further below. Two tensile members 44, 46 may be secured between the annulus 52 of mitral valve 54 and the apex 56 of left ventricle 28. A button 58 may be used at the apex for securement purposes and may bear against the intersections of tensile members 40c, 40f. Transverse internal tensile members 48, 50  
15 may extend crosswise as best shown in Figure 3 between the outer wall of left ventricle 28 and the interventricular septum 32. Tensile members 48, 50 may be secured to any of the outer tensile members, as well as to plate 42 at opposite ends, or may be secured to the walls of the heart itself. Similar internal tensile members may be used in the right ventricle, although  
20 this is not preferred for the reason that it may not be necessary as the motion of the right ventricle is primarily in a direction toward the interventricular septum. Also, it will be understood that tensile members 44, 46 may be secured in other ways within left ventricle 28, such as by being secured to an annuloplasty ring or to a replacement mitral valve.

Figure 3A illustrates an alternative passive/active heart assist device 10' taking the form of a modified version of device 10 shown in Figures 2 and 3. Device 10' includes various elements having like reference numerals in Figure 3, but adds an inflatable bladder 47 which  
5 may be positioned between flexible tensile member 40a and the outside wall of left ventricle 28. Bladder 47 is connected through a suitable conduit 49 to a fluid pump which may direct air or other fluid into bladder 47 in a cyclical manner. Inflation and subsequent deflation of bladder 47 will contract left ventricle 28 against the support provided by internal  
10 support member 42 to expel blood and subsequent deflation will allow left ventricle 28 to expand and refill with blood. Alternatively, an internal bladder 53 may be provided and cyclically inflated and deflated, as shown, to expel blood from left ventricle 28 and allow subsequent refilling of the ventricle with blood. Bladder 53 would likewise be supplied with air or  
15 other appropriate fluid through a catheter from a suitable pump device (not shown).

As further shown in Figure 4, a series of pulley members 60 may be used with a single actuator 62, such as an electric solenoid or pneumatic actuator having a reciprocating element 62a attached to a series  
20 of cables or tensile members 63 extending through pulley members 60. Actuator 62 may be contained in a suitable pouch 64 or other containment structure and springs 66, 68 may be used to control the amount of compression applied by cables or tensile members 63. As reciprocating member 62 moves inwardly in the direction of the arrow in Figure 4, cables

or tensile members 63 will move under tension and cause simultaneous compression of the right and left ventricles.

Figure 5 illustrates an embodiment similar to Figure 4, but using multiple actuators 70, 72, 74 for independently applying compression to heart 14. Actuator 70 applies transverse compression to an upper portion of heart 14, while actuator 72 applies transverse compression to a lower portion of heart 14. Actuator 74 applies compression in a lengthwise direction. As with the other embodiments, suitable flexible tensile members, such as cables extending over or within straps, are provided to apply the compression upon operation of actuators 70, 72, 74.

Figure 6 illustrates another alternative heart support and assist device 80 formed by a generally spiral shaped tensile member 82 extending around heart 14. Tensile member 82 preferably comprises an outer hollow member 84 and an inner movable cable 86 connected at one end to a suitable actuator 88 affixed to a jacket 90 and at an opposite end being rigidly affixed by a connector 92 to jacket 90. An upper end of jacket 90 may be suitably connected to heart 14, as through stitching 94. As shown in Figure 6, two coils of the spiral tensile member 82 extend into right ventricle 20 and bear against interventricular septum 32 before exiting heart 14 and again extending around the outside of jacket 90. The remaining upper and lower sets of coils extend around the outside of jacket 90. This configuration is intended to compress both the right and left ventricles 20, 28 of heart 14, while focusing on left ventricle 28, which is the ventricle with which most heart patients experience problems.

Actuator 88 may be a conventional linear electric actuator that cyclically pulls on cable 86 in concert with the patient's own natural heart rhythm or as activated by a conventional pacing device which sets the patient's heart rhythm. It will also be appreciated that this type of generally spiral-shaped support device may be used in a passive manner without an active pump assist function. The spiral shape can be used for adjusting the tightness of tensile member 82 against the heart for achieving the proper amount of support.

Figure 7 illustrates another alternative heart assist device 100 comprised of a cup having two halves 102, 104 which together receive a patient's heart 14. Each half 102, 104 is respectively comprised of an outer shell and innerinflatable bladder combination 106, 108-and 110, 112. One or more internal support members 114, 116 extend generally between halves 102, 104 through heart 14. Support members 114, 116 are intended to extend through one or both of the left and right ventricles (not shown) of heart 14 and bear against the interventricular septum (not shown), as with the support members used in other embodiments of the invention. This provides support for the interventricular septum during compression of the heart without a significant amount of trauma to the heart muscle. Support members 114, 116 may, for example, be one or more rigid plates or flexible straps, or other suitable support members. Respective connectors 118, 120 may be provided to affix halves 102, 104 together. In this illustrative example, connectors 118 extend through holes 114a, 116a in support members 114, 116 and into connectors 120 of half

104 to connect device 100 firmly against heart 14. Additional connectors or other means may be used to ensure that device 100 remains in position around heart 14. Once in position, bladders 108, 112 may be cyclically inflated and deflated to compress the left and right ventricles of heart 14 while the opposite side of one or each of the ventricles is supported by members 114, 116. A pump 124 may be connected to bladders 108, 112 for selectively inflating and deflating bladders 108, 112 with an appropriate fluid, such as air or liquid. Again, pump 124 may be activated in correspondence with the patient's heart rhythm, such as through the use of a conventional electrical pacing device.

Figure 8 illustrates another alternative heart assist device 130 comprised of a flexible strap system 132 configured for disposition around a patient's heart 14 and connected with a suitable internal support member 134 for bearing against one side of the interventricular septum within one of the heart's ventricles, as previously discussed. In this embodiment, at least one pump 136 is directly connected through a suitable conduit, such as a catheter 138, to one of the ventricles of heart 14. For example, pump 136 may be connected to the left ventricle of heart 14 for directly pumping blood into the left ventricle to assist with the movement of blood through heart 14. Likewise, another pump 140 may be directly connected to the right ventricle of heart 14 through another conduit 142 for assisting with blood flow through the right ventricle. Pumps 136 and 140 may obtain blood from any suitable vessel within the patient's body.

Figure 9 illustrates a passive heart support device 150 shown implanted on a heart 14 and, specifically, around left ventricle 28. Support device 150 includes a flexible mesh or web material 152 serving as an external support member around left ventricle 28 and a plurality of internal support members 154, 156, 158 extending through right ventricle 20 and against interventricular septum 32. Internal support members 154, 156, 158 may be attached to mesh or web element 152 in numerous ways, such as by stitching or other quicker connection means. At least one end of internal support members 154, 156, 158 will be detached from mesh or web element 152 for extension through right ventricle 20 during implantation and then adjusted for tightness on heart 14 and secured to mesh or web element 152 preferably at an opposite side of the heart. If necessary, an external sheath 160, which may be elastic in nature, may receive heart 14 after attaching device 150, as a further securement means. Sheath 160 may include an open end 162 and a closed end 164.

Figure 10 illustrates an alternative device 150', which is similar to device 150, and includes a mesh or web element 152 for supporting an external portion of the heart. A plurality of internal support members 162a, 162b and 164a, 164b are connected to opposite sides of mesh element 152. Device 150', for example, may be introduced into a patient's chest through a relatively small port hole and, using catheter-based devices, internal support elements 162a, 162b and 164a, 164b may be secured across the interventricular septum as generally shown in Figure 9.



Figure 11 illustrates another alternative passive support device 170 comprising an external support portion 172, which may again be another flexible mesh or web element 172 and internal support member 174, 176. In this embodiment, support member 176 extends only partially  
5 along the interventricular septum 32 and internal support member 174 extends through septum 32 and connects with external support member 172 at one end and internal support member 176 at an opposite end. Support members 174 and 176 may be separate members which are connected together or may be a single integral member, as shown.  
10 Additional support members 178, 180, shown in phantom, may be optionally used in addition to or as an alternative to internal support member 174.

Figures 12, 12A and 13A-B illustrate a partially catheter-based implantation device and method. Specifically, a catheter 190 having a  
15 sharpened portion 192 is introduced from a vein 194, for example, originating in the groin of the patient. Catheter 190 enters right atrium 18 and pierces through wall 18a into right ventricle 20. A heart support device 200 may comprise a cable which, for example, may include a sheath (not shown) and which acts as both an external and internal support  
20 members for heart 14. Catheter 190 may be used to introduce opposite ends of support device 200 through opposite walls of right ventricle 20, as shown in Figure 13A. Piercing member 192 may, for example, extend to fully pierce through the wall of the heart, or device 200 itself may pierce through the wall of heart 14. Device 200 includes two looped ends 202,

204 with at least one of these ends being collapsible in the form of a tightening noose. In the embodiment shown, this is end 204. A tool 210 may be introduced through a small port hole in the patient's chest and includes a hook member 212. Tool 210 extends through loop 204 and  
5 hook 212 may be used to grasp looped end 202 to pull it through looped end 204. Looped end 204 is then tightened as shown in Figure 13B so that an internal portion 200a of device 200 lies against septum 32 within right ventricle 20 and another portion 200b of device 200 lies on the external surface of heart 14 adjacent left ventricle 28.

10                Figures 14A and 14B illustrate another alternative embodiment of the invention in the form of a completely catheter-based fixation method using first and second flexible gripper members 220, 222 which may be introduced through the same catheter (not shown) or separate catheters (not shown). Gripper members 220, 222 include jaws 220a, 222a which  
15 may be actuated to grip the ends of a support member 230. Support member 230 includes respective ends 230a, 230b retained between jaws 220a and 222a. As with the previous embodiment, gripper members 220, 222 may be introduced into right ventricle 20, pierced through the heart wall 14a adjacent septum 32 and directed around the outside of left  
20 ventricle 28. Support member 230 includes ratchet-type connector ends 230a, 230b which may be connected together as shown in Figure 14B with end 230b being inserted into end 230a and retained by the teeth on end 230b. Jaws 220a, 222a release ends 230a, 230b and then are used to grip the opposite end 230a, 230b after engagement to allow pulling of

the ends 230a, 230b in opposite directions for tightening and locking device 230 around left ventricle 28. It will be appreciated that other forms of the device, as well as other forms of the connecting and locking elements may be used as well. Also, other portions of the heart may be supported and this type of catheter-based insertion method and device may be used in conjunction with other supporting and/or assisting devices.

Figure 15 illustrates another alternative heart support device 240 comprised of three flexible support members 242, 244, 246 extending around the outside of left ventricle 28. Portions 242a, 244a and 246a extend through the wall of the heart into right ventricle 20 and connect with a support plate 248 lying against septum 32.

Figures 16 and 17 illustrate another alternative passive heart support device 250 comprising a substantially rigid annular member having two ends (not shown) affixed to one another by a connector 252. Two inwardly projecting portions 254, 256 exert pressure selectively to small areas of the heart muscle. Specifically, for example, portions 254, 256 may be positioned to exert selective support to the papillary muscle regions of the heart, or to other weakened areas of the heart depending on the particular needs of the patient. Support member 250 is rigid enough to provide such support in a manner that prevents undesirable, outward bulging of the heart muscle. As apparent from Fig. 16, device 250 may also be configured to extend only around the outside surface of the heart.

While the present invention has been illustrated by a description of preferred embodiments and while these embodiments have

been described in some detail, it is not the intention of the Applicants to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. The various features and concepts of the invention may be used

5 alone or in numerous combinations within each embodiment or between the embodiments depending on the needs and preferences of the user. This has been a description of the present invention, along with the preferred methods of practicing the present invention as currently known. However, the invention itself should only be defined by the appended claims, wherein

10 we claim:

1.           A device for supporting a heart having left and right ventricles separated by an interventricular septum, the device comprising:  
  
                an external, flexible mesh element configured to be placed around at least a portion of the heart of a patient, and  
  
5               an internal support member configured to be received within one of the left and right ventricles and against the interventricular septum, said internal support member being coupled to said external, flexible mesh element.  
  
2.           The device of claim 1, wherein said external, flexible mesh  
10           element further comprises intersecting fabric elements.  
  
3.           The device of claim 1, wherein said external, flexible mesh element further comprises intersecting polymeric elements.  
  
4.           The device of claim 1, wherein said internal support member further comprises a flexible strap connected with said external, flexible  
15           mesh element.  
  
5.           The device of claim 4, wherein said strap is adjustable to allow adjustable application of pressure to the heart.

6. The device of claim 1 further comprising multiple internal support members, each internal support member being formed as a flexible strap coupled to said external, flexible mesh element.

7. The device of claim 1, wherein said external, flexible mesh  
5 element is configured to overly only a portion of one of said ventricles and said internal support member includes a first portion configured to lie against the interventricular septum in the other of said ventricles and a second portion configured to extend through said one ventricle and connect with said external, flexible mesh element.

10 8. A device for supporting a heart having left and right ventricles separated by an interventricular septum, the device comprising:

an external, flexible mesh element to be placed around at least a portion of the heart of a patient,

an internal support member configured to be received within  
15 one of the left and right ventricles and against the interventricular septum, said internal support member being coupled to said external, flexible mesh element member,

wherein said external, flexible mesh element is configured to overly only a portion of one of said ventricles and said internal support  
20 member includes a first portion configured to lie against the interventricular septum in the other of said ventricles and a second portion configured to

extend through said one ventricle and connect with said external, flexible mesh element.

9. A system for supporting a heart having a left and right ventricles separated by an interventricular septum, the system comprising:

5 at least one catheter,  
at least one flexible support member configured to be carried within said catheter and having first and second connecting ends, said flexible support member capable of being introduced through said catheter into one of said ventricles, around an external portion of the other of said  
10 ventricles and secured using at least one of said connecting ends such that a portion of the flexible support member supports the interventricular septum within said one ventricle and another portion of the flexible support member supports the external portion of the other ventricle.

10. The system of claim 9, wherein said connecting ends are  
15 configured to be connected to each other.

11. The system of claim 10, wherein at least one of said connecting ends includes a locking element for engaging the other connecting end and locking the first and second connecting ends together.

12. The system of claim 9, wherein one of said connecting ends is configured to receive the other connecting end in an adjustable manner to allow adjustable pressure to be applied around the other ventricle.
13. The system of claim 9, wherein said connecting ends each  
5 comprise loops.
14. The system of claim 9, further comprising two of said catheters, each catheter including a gripping element for gripping a respective connecting end.
15. A device for supporting a heart, said device comprising a rigid  
10 annular band configured to have at least a portion bear against an external surface of the heart, said portion including an inward projection for supplying selective inward pressure against a selected area of the external surface of the heart.
16. The device of claim 15, further comprising a plurality of said  
15 inward projections disposed at spaced apart locations of said rigid annular band.
17. The device of claim 15, wherein said rigid annular band is configured to lie entirely outside the heart against the external surface.



18. A device for supporting a heart having left and right ventricles separated by an interventricular septum, the device comprising:
- a first cup configured to receive a first portion of the heart proximate the left ventricle,
  - 5 a second cup configured to receive a second portion of the heart proximate the right ventricle,
  - at least one internal support member configured to extend generally between the first and second cups, through one of the left and right ventricles, and against the interventricular septum, and
  - 10 a connector for connecting said first and second cups together with the heart received between the first and second cups.
19. The device of claim 18, wherein said internal support member comprises a flat plate.
20. The device of claim 18, wherein said internal support member
- 15 comprises a flexible strap.
21. The device of claim 18, wherein opposite ends of said internal support member are retained between opposing edges of said first and second cups.

22. A device for assisting a heart having left and right ventricles separated by an interventricular system, the device comprising:

a plurality of flexible external tensile members adapted to be wrapped circumferentially around at least a portion of one of the left and  
5 right ventricles of the heart,

an internal support member configured to be received within at least one of the left and right ventricles against the interventricular septum and coupled to at least one of the plurality of flexible external tensile members, and

10 at least one powered actuator connected with the plurality of flexible external tensile members and operative to pull the tensile members with a tensile force respectively against at least one of the left and right ventricles to apply compression to the heart and assist with expelling blood therefrom.

15 23. The heart assist device of claim 22, wherein the first and second external tensile members respectively further comprise:

a plurality of tensile members configured to extend around the left ventricle,

a plurality of tensile members configured to extend around the  
20 right ventricle, and

wherein each of the pluralities of tensile members is secured at least indirectly to said support member.

24. The heart assist device of claim 23, wherein said support member further comprises a flat plate covered in a biocompatible material for inhibiting blood clotting.

25. The heart assist device of claim 23 further comprising:  
5 a plurality of pulley members coupled with said tensile members and operating to allow a single powered actuator to pull multiple tensile members.

26. The heart assist device of claim 22 further comprising at least one internal tensile member configured to be connected lengthwise  
10 between the fibrous skeleton of the heart proximate the mitral valve or aortic valve and the apex of the left ventricle, said internal tensile member configured to inhibit lengthening of the left ventricle when the powered actuator pulls said tensile members to compress the left and right ventricles.

15 27. The heart assist device of claim 22, wherein said tensile members are contained in sleeves to prevent cutting of the heart by said tensile members during use.

28. The heart assist device of claim 22 further comprising a plurality of coronary obstruction preventing members configured to be  
20 disposed between said tensile members and coronary arteries on the

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outside of the heart for preventing the coronary arteries from being compressed and obstructed by the tensile members.

29. The heart assist device of claim 22, wherein at least one of said plurality of flexible external tensile members is configured generally in a spiral shape to facilitate the application of compression to the heart.

30. A device for assisting a heart having a plurality of ventricles separated by an interventricular septum, the device comprising:  
an external member configured to receive at least a portion of a heart,  
at least one support member extendable between opposite sides of the external member and configured to extend across and against one side of the interventricular septum,  
a bladder configured for disposition between the external member and an outside surface of the heart; and  
a pump for selectively inflating and deflating said bladder to apply compression to at least one of the ventricles as the support member supports a side of the interventricular septum opposite to said one ventricle.

31. The device of claim 30, wherein said external member comprises a cup.

32. The device of claim 31, wherein said cup further comprises a first half configured for disposition around a left ventricle of the heart and a second half configured for disposition around a right ventricle of the heart.

33. The device of claim 32, wherein said support member is  
5 connected at a position generally between the first and second halves of said cup.

34. The device of claim 33 further comprising a second support member connected at a position generally between the first and second halves of said cup.

10 35. The device of claim 32, wherein each half of the cup contains an inflatable bladder for respectively compressing the left and right ventricles of the heart.

36. The device of claim 30, wherein said external member comprises at least one strap.

15 37. A method of supporting a heart having left and right ventricles separated by an interventricular septum, the method comprising:  
placing an external support element around an external surface of the heart adjacent at least one of the left and right ventricles,

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placing an internal support element within the other of the left and right ventricles and against the interventricular septum,

adjusting the force of the external support element against the external surface of the heart by way of an adjustable connector on at least

5 one of the internal and external support elements, and

retaining the internal and external support elements on the heart at the adjusted force.

38. A method of supporting a heart having a plurality of walls, the method comprising:

10 introducing at least one catheter into the heart,

introducing a heart support member through the catheter and into the heart, and

securing the heart support member adjacent at least one of the walls of the heart to restrict movement of the one wall during a heartbeat.

15 39. The method of claim 38, wherein the heart includes left and right ventricles separated by an interventricular septum, and said catheter is introduced into the right ventricle.

40. The method of claim 39, further comprising:

20 securing the heart support member adjacent the interventricular septum within the right ventricle.

41. The method of claim 39, further comprising:  
supporting an outer surface of the left ventricle using the heart  
support member.
42. A method of supporting a heart having a plurality of walls, the  
5 method comprising:  
securing a support member adjacent a weakened area of at  
least one of the walls, and  
applying discreet pressure to a selected area of the weakened  
area using an inwardly projecting portion of the support member.
- 10 43. The method of claim 42, wherein the weakened area is an  
area containing a papillary muscle of the heart.
44. The method of claim 42, wherein the support member further  
comprises an annular band of rigid material, and the method further  
comprises:  
15 securing a first portion of the band adjacent an external wall of  
the heart, and  
securing a second portion of the band adjacent an internal wall  
of the heart.

45. The method of claim 44, wherein the heart includes left and right ventricles separated by an interventricular septum and wherein:

the first portion of the band is secured adjacent the interventricular septum of the heart, and

5 the second portion of the band is secured adjacent an external wall of at least one of the right and left ventricles.

46. A method of assisting the pumping action of the heart having left and right ventricles separated by an interventricular septum, the method comprising:

10 inserting a support member within one of the right and left ventricles and against the interventricular septum,

encircling the outside of the other of the right and left ventricles with at least one external member, and

coupling the external member with the support member, and

15 compressing said one ventricle in a direction toward the interventricular septum.

47. The method of claim 46, wherein the compressing step is performed by inflating a bladder between the external member and an outside wall of the heart.

20 48. The method of claim 46, wherein the compressing step is performed by pulling said external member with a tensile force.



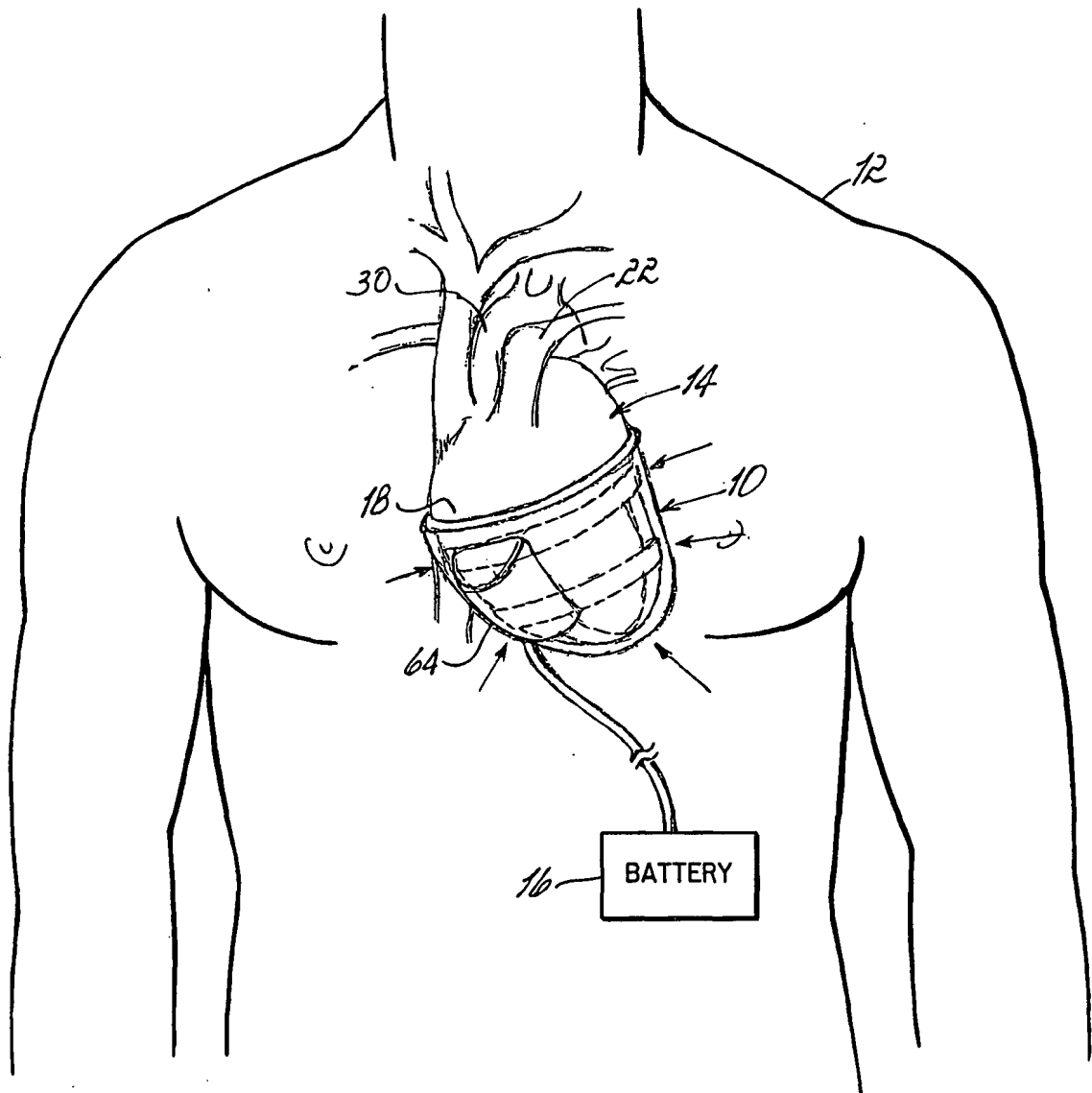


FIG. 1

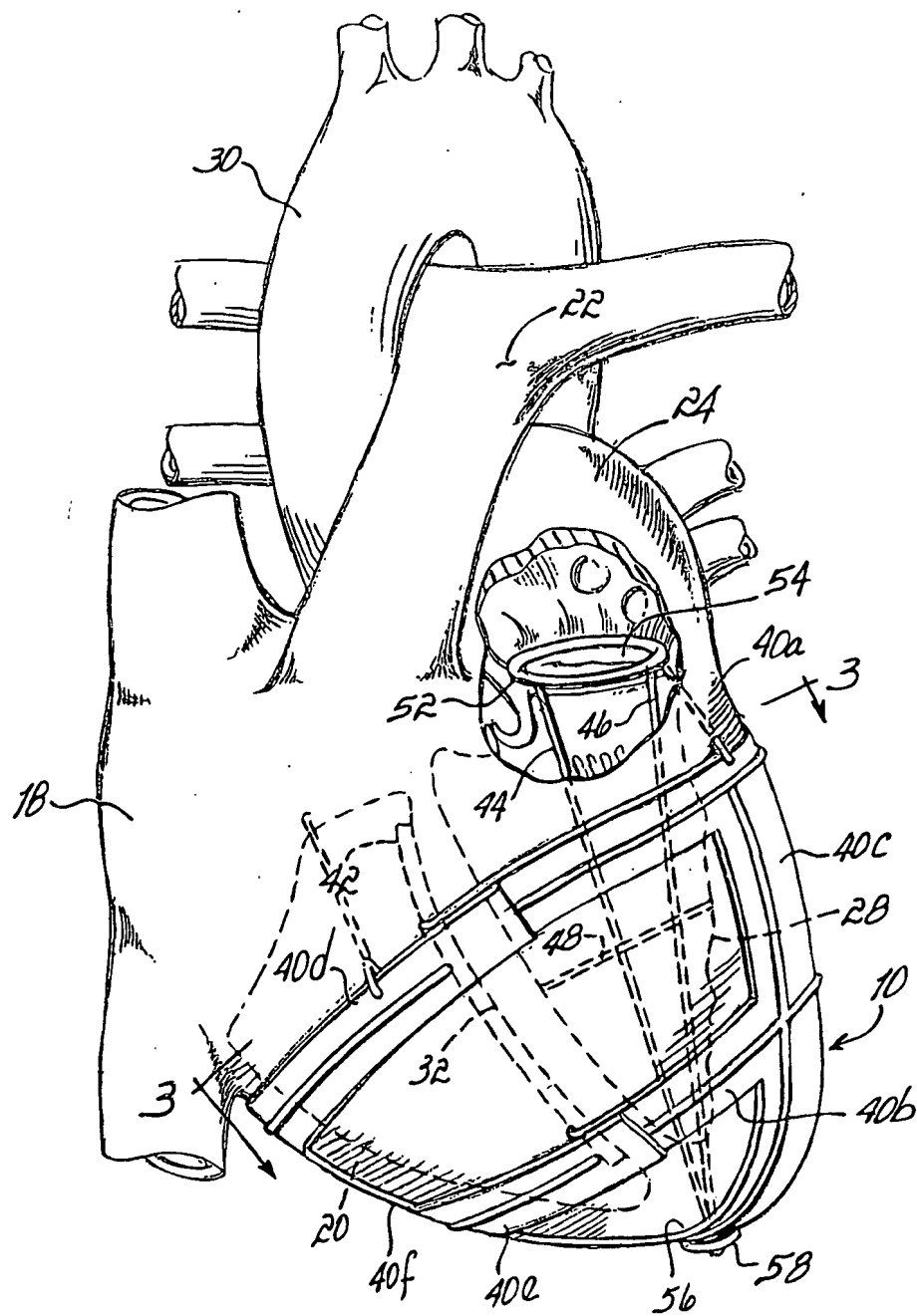


FIG. 2

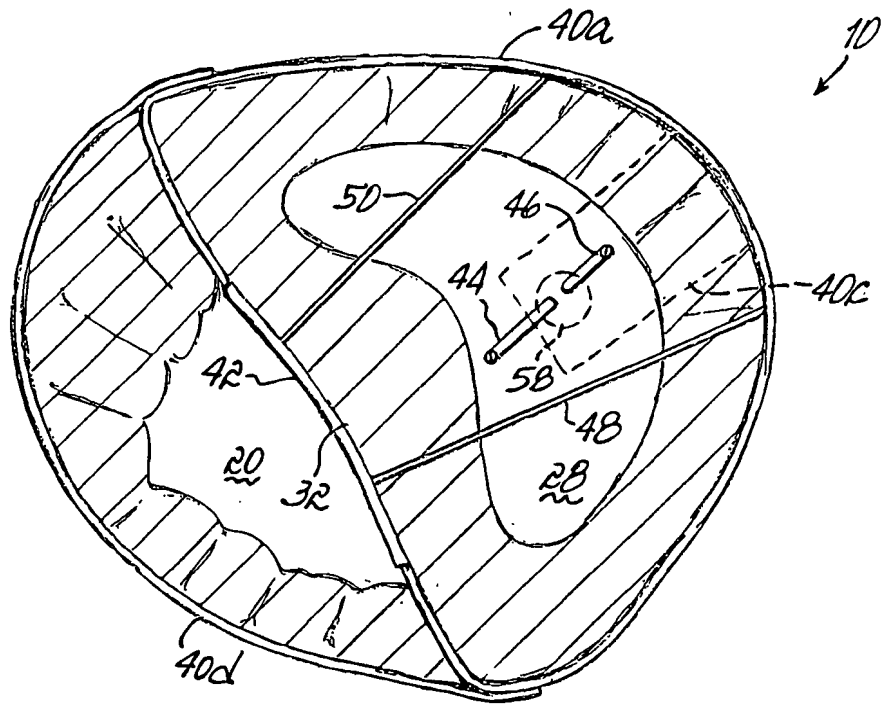


FIG. 3

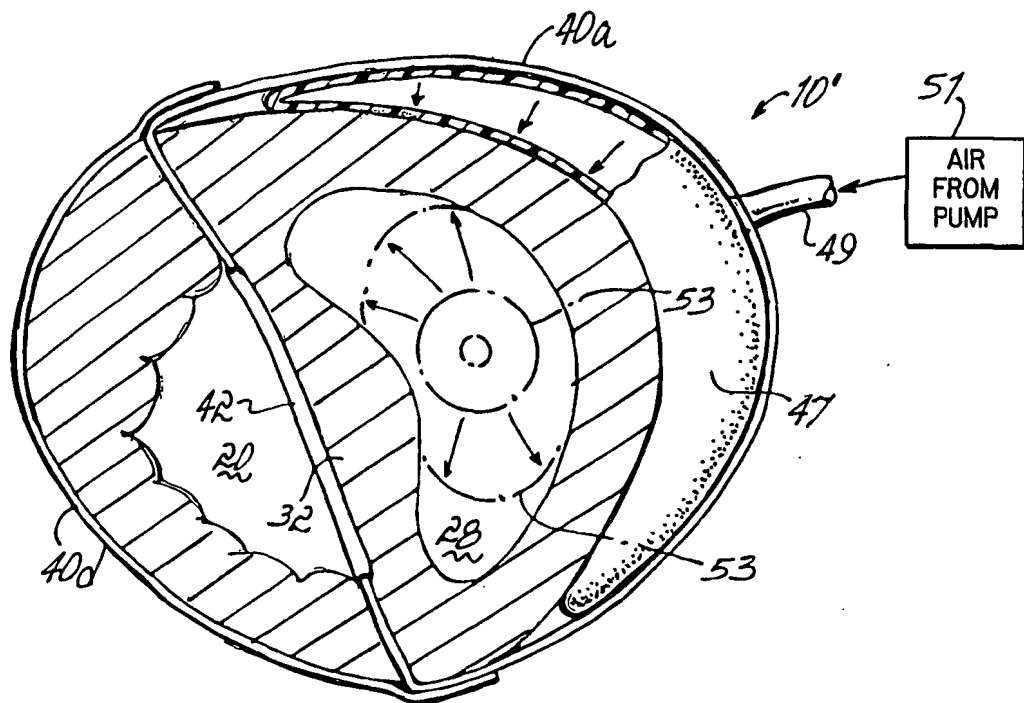


FIG. 3A

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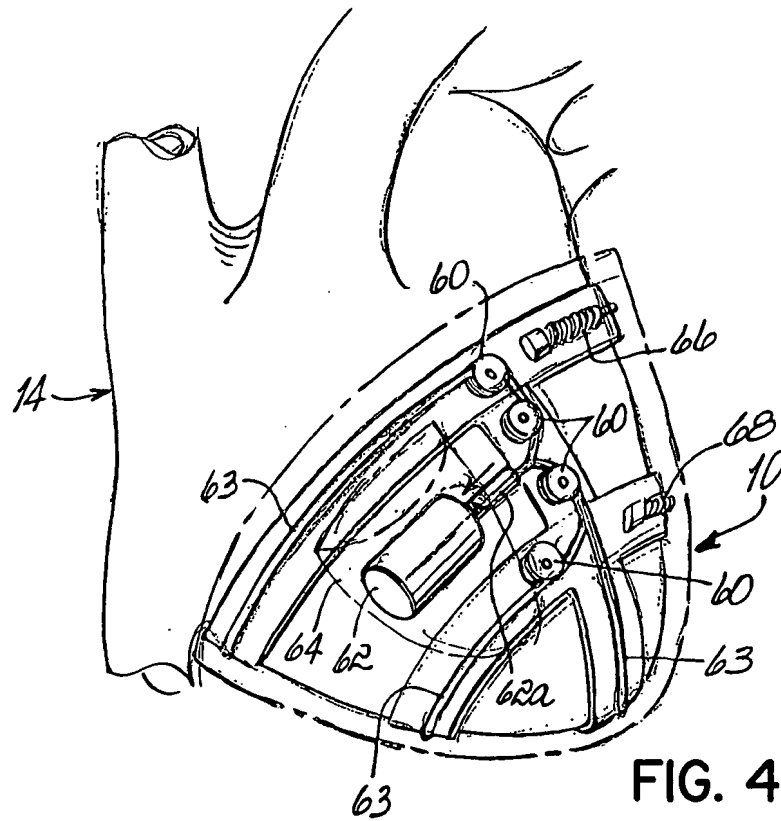


FIG. 4

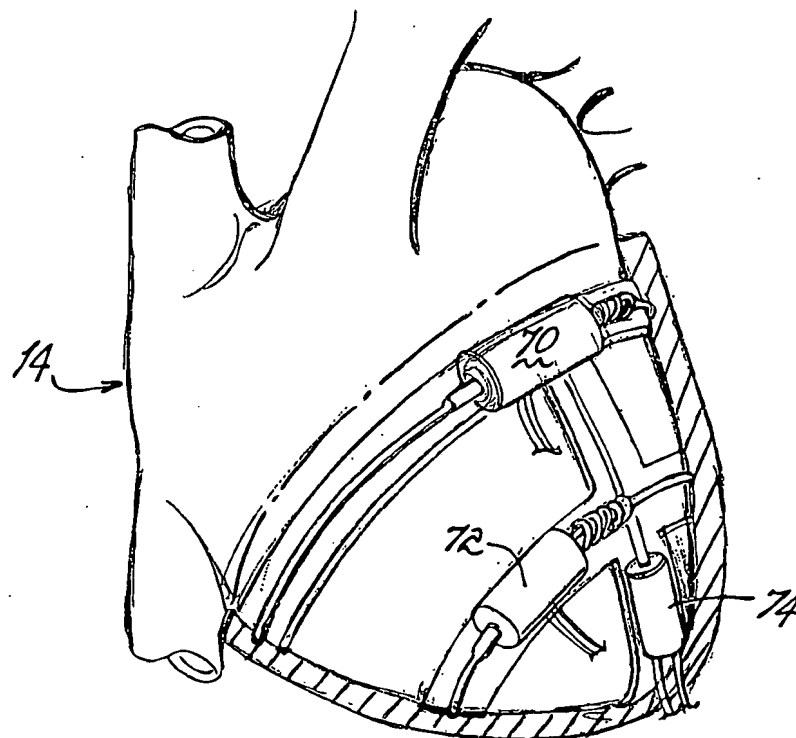
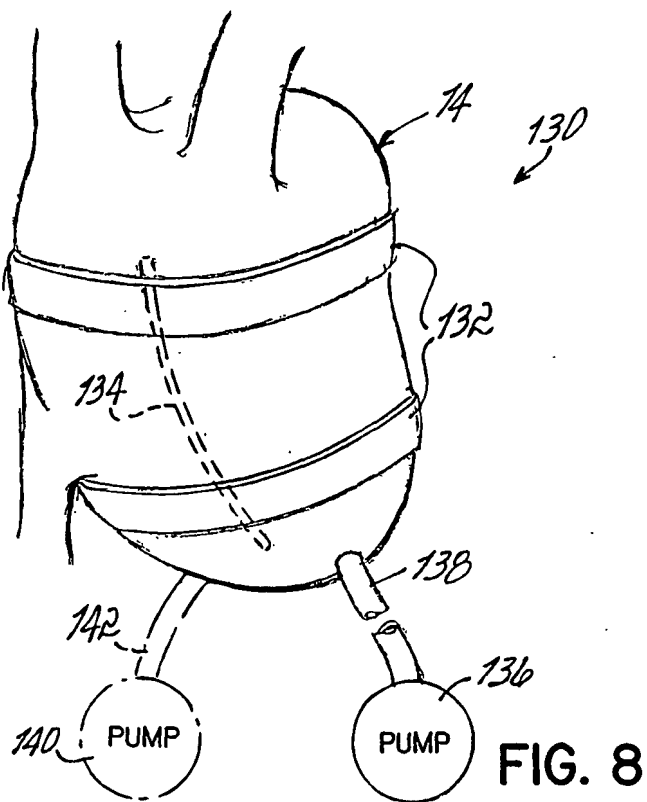
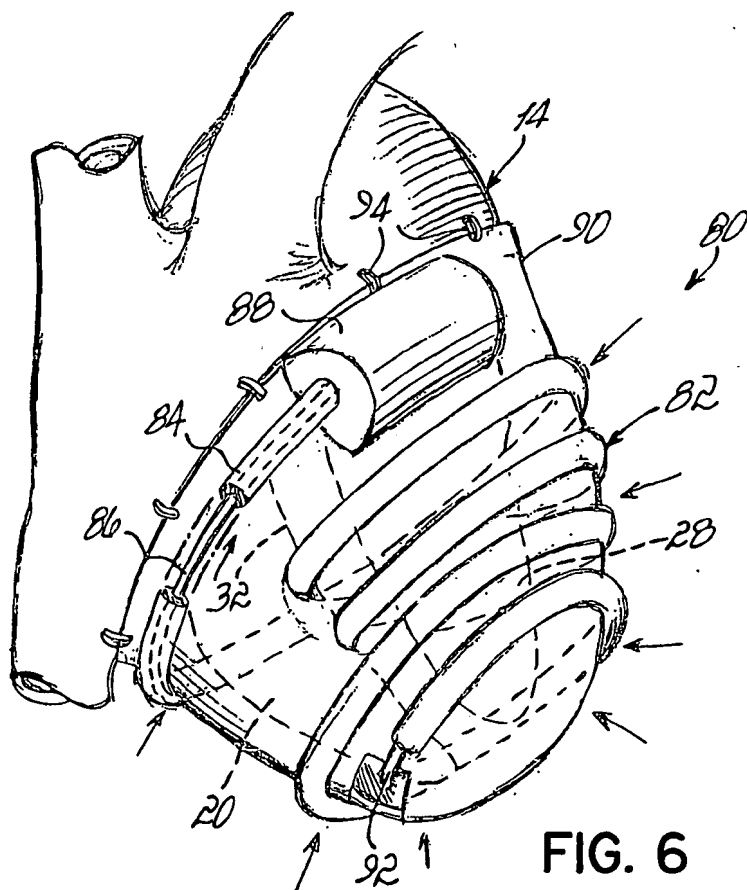
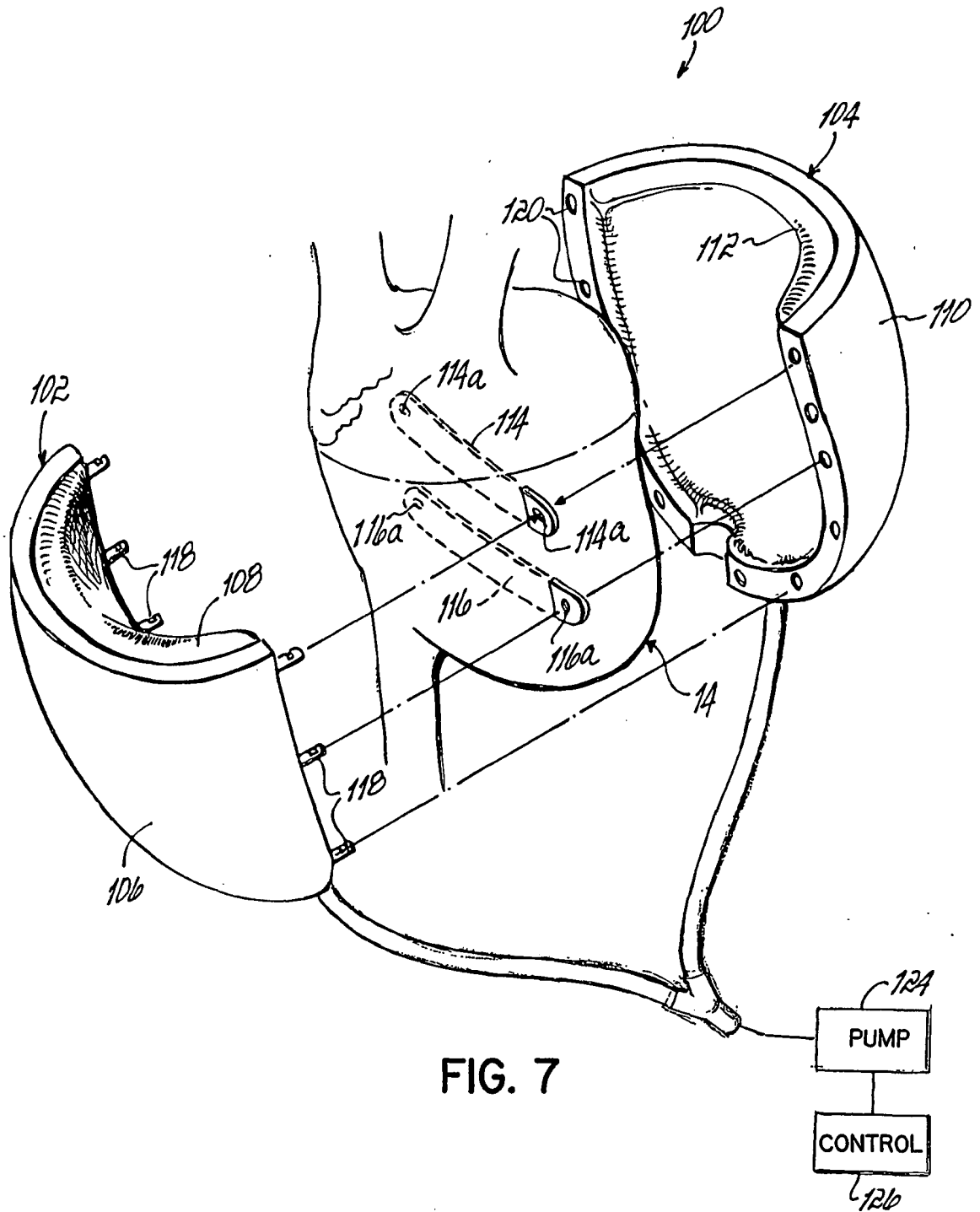


FIG. 5

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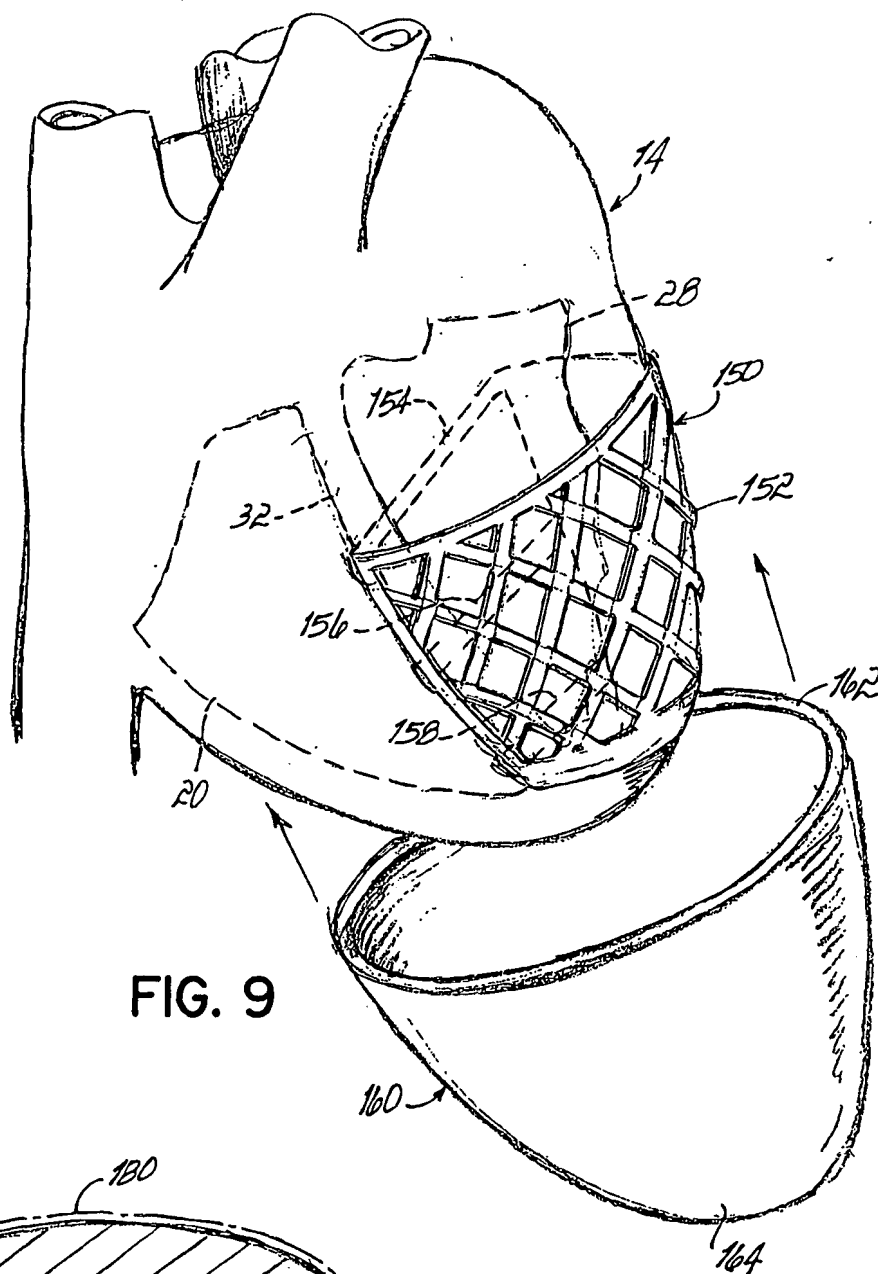


FIG. 9

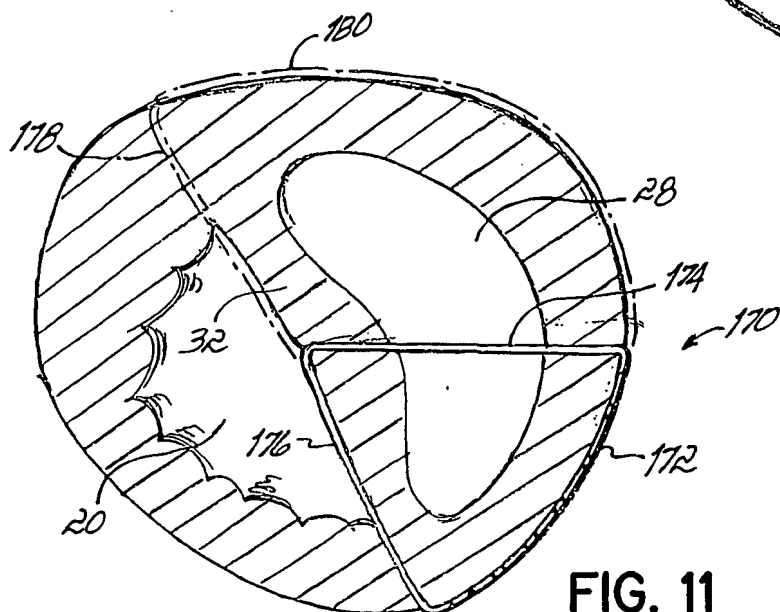


FIG. 11

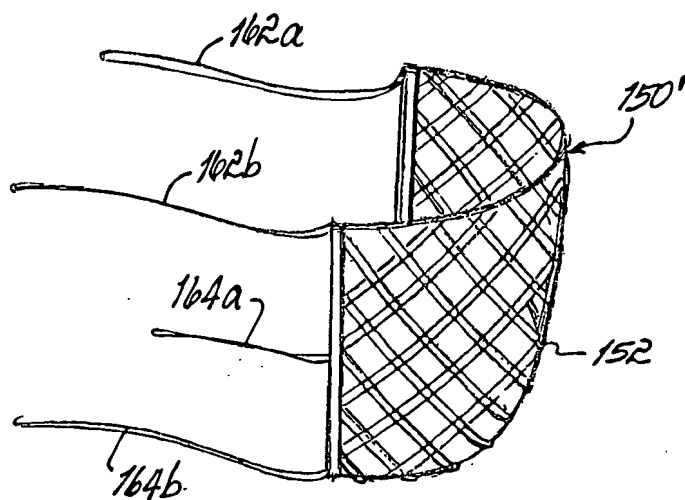


FIG. 10

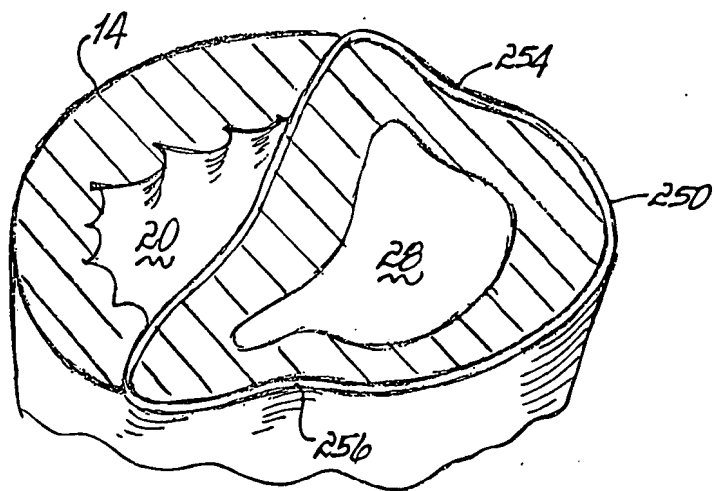
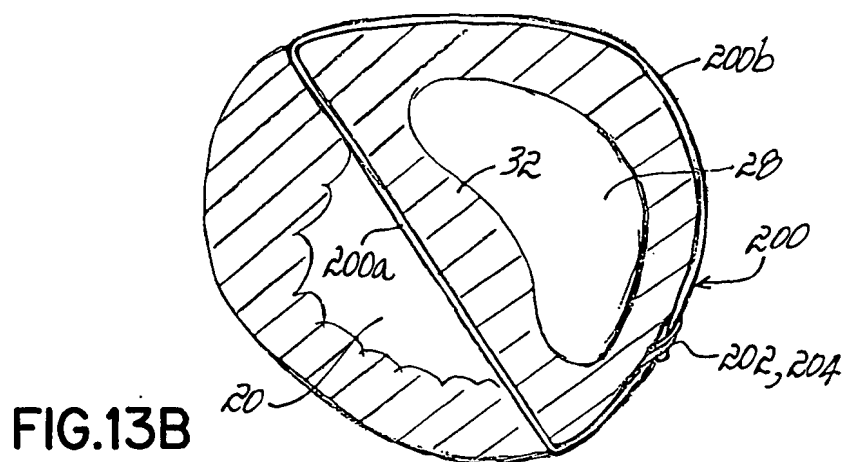
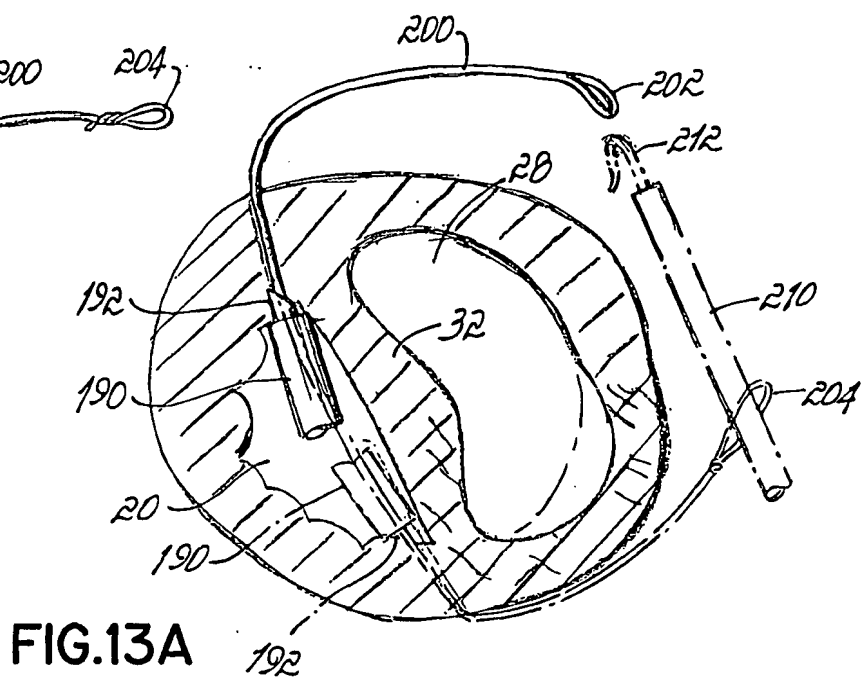
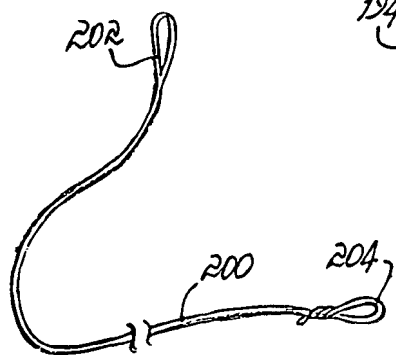
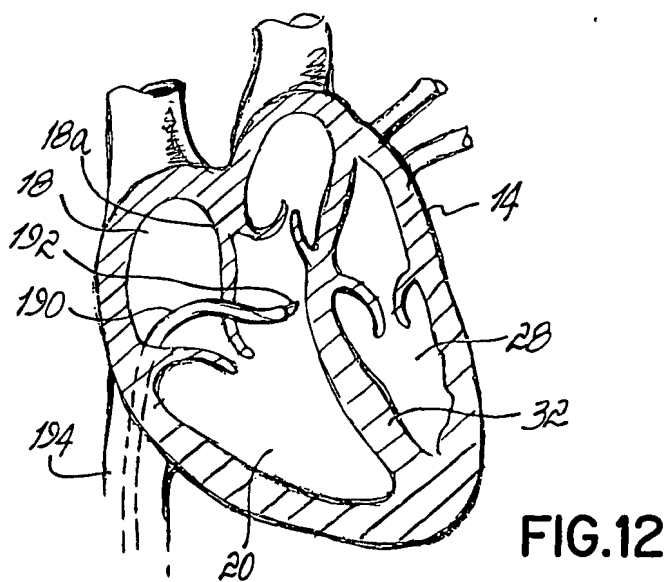


FIG. 17





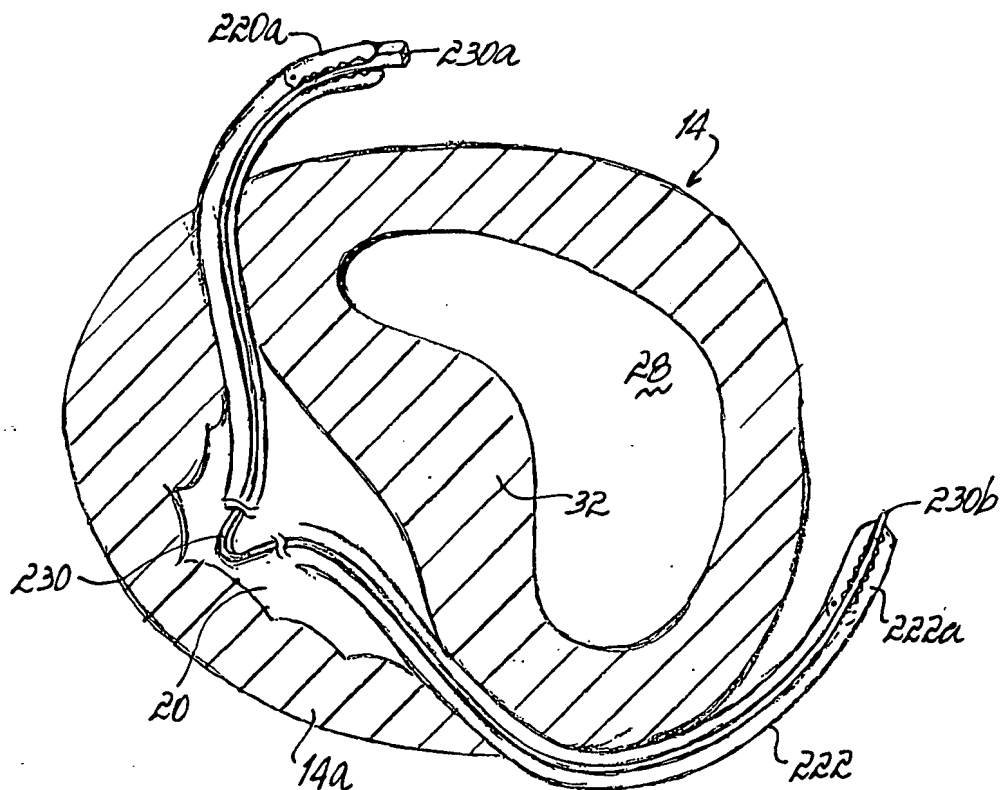


FIG.14A

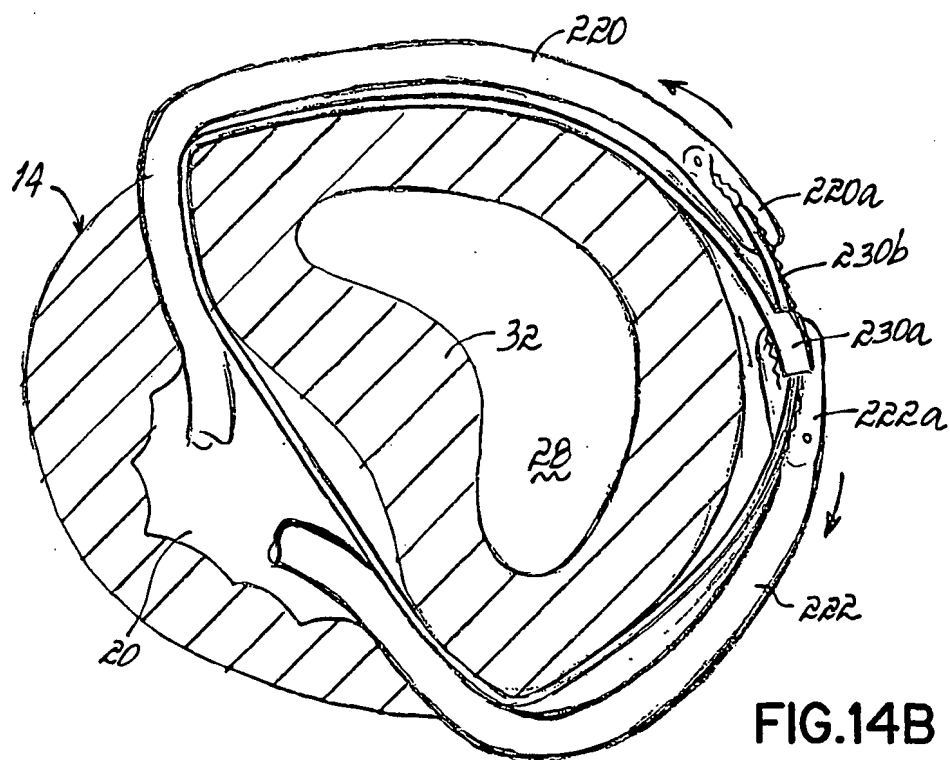
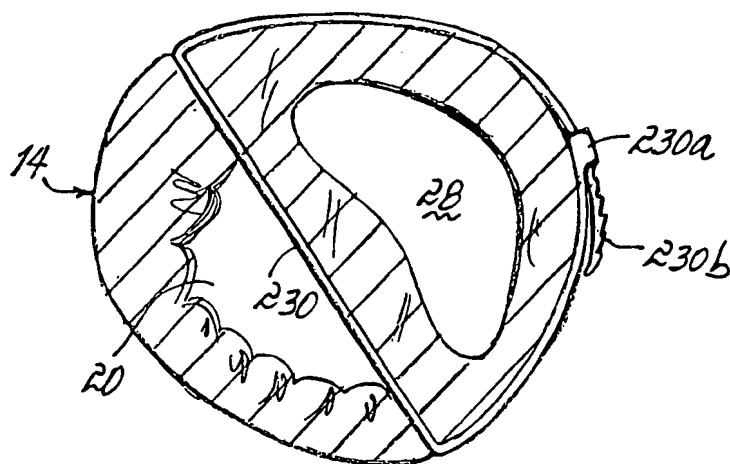


FIG.14B



**FIG.14C**

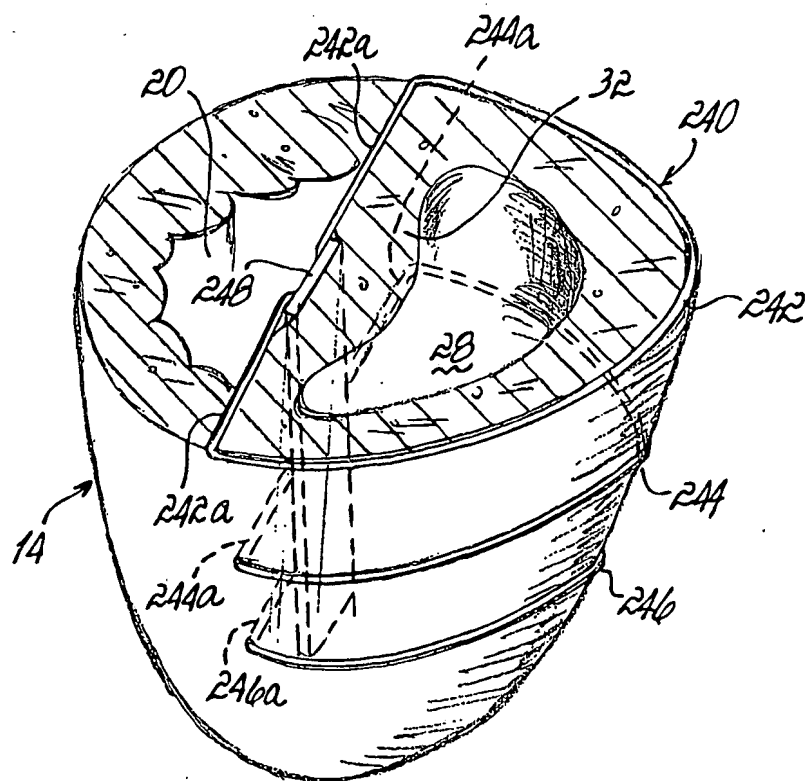


FIG.15

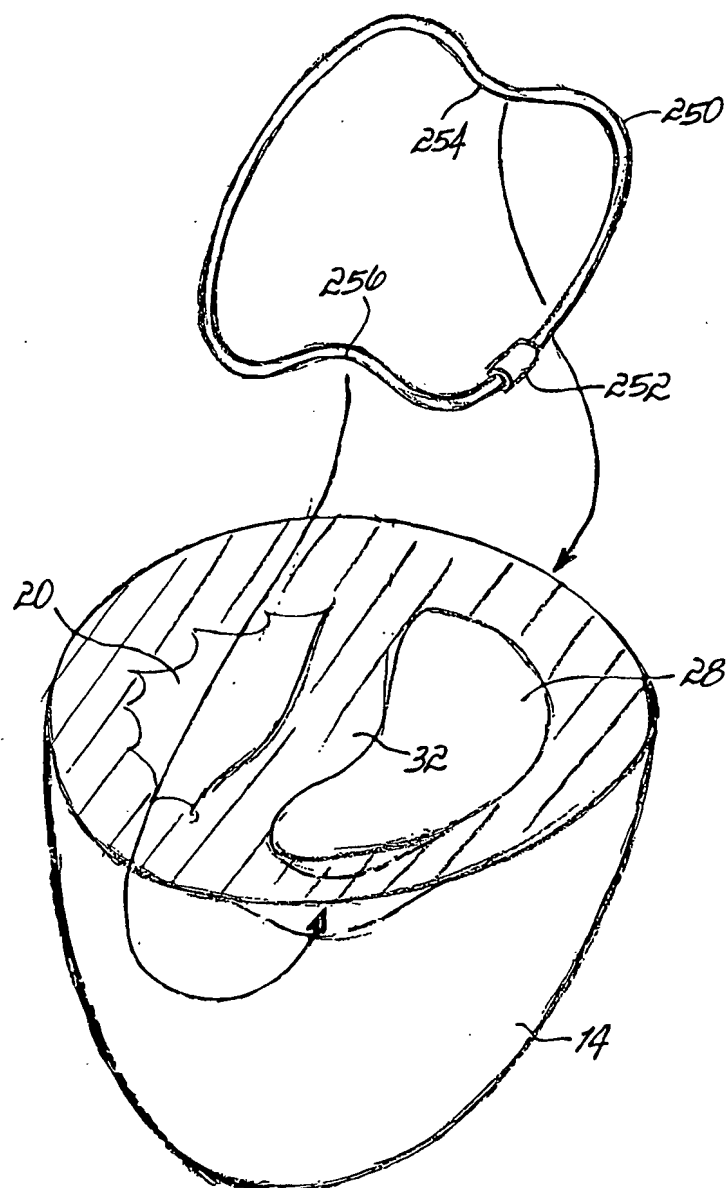


FIG.16

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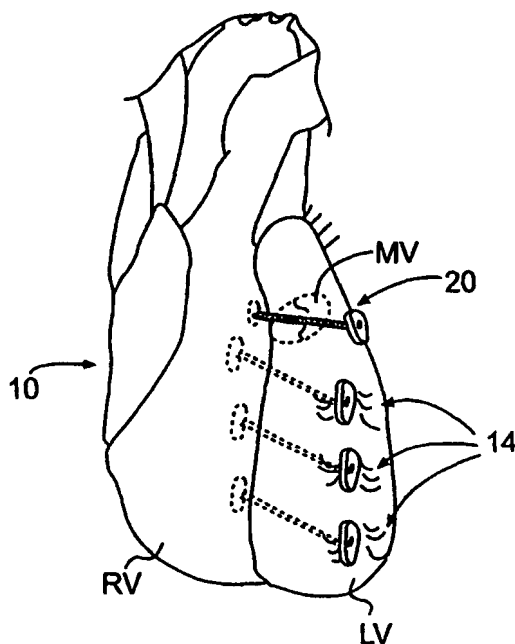
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[Continued on next page]

(54) Title: METHODS AND DEVICES FOR IMPROVING MITRAL VALVE FUNCTION



(57) Abstract: The various aspects of the invention pertain to devices and related methods for treating heart conditions, including, for example, dilatation, valve incompetencies, including mitral valve leakage, and other similar heart failure conditions. The devices and related methods of the present invention operate to assist in the apposition of heart valve leaflets to improve valve function. According to one aspect of the invention, a method improves the function of a valve of a heart by placing an elongate member transverse a heart chamber so that each end of the elongate member extends through a wall of the heart, and placing first and second anchoring members external the chamber. The first and second anchoring members are attached to first and second ends of the elongate member to fix the elongate member in a position across the chamber so as to reposition papillary muscles within the chamber.

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## METHODS AND DEVICES FOR IMPROVING MITRAL VALVE FUNCTION

### BACKGROUND OF THE INVENTION

#### Field of the Invention

The present invention relates to devices and related methods for improving the function of heart valves, and more particularly to devices and related methods that passively assist in the apposition of heart valve leaflets to improve valve function of poorly functioning valves.

#### Description of the Related Art

Heart failure is a condition whereby the left ventricle becomes enlarged and dilated as a result of numerous etiologies. Initial causes of heart failure include chronic hypertension, myocardial infarction, mitral valve incompetency, and other dilated cardiomyopathies. With each of these conditions, the heart is forced to overexert itself in order to provide the cardiac output demanded from the body during its various demand states. The result is an enlarged left ventricle.

A dilated heart, and particularly a dilated left ventricle, can significantly increase the tension and/or stress in the heart wall both during diastolic filling and systolic contraction, which contributes to ongoing dilatation of the chamber. Prior treatments for heart failure include pharmacological treatments, assist devices such as pumps, and surgical treatments such as heart transplant, dynamic cardiomyoplasty, and the Batista partial left ventriculectomy. These prior treatments are described briefly in U.S. Patent No. 5,961,440 to Schweich, Jr. et al., issued October 5, 1999 and entitled "Heart Wall Tension Reduction Apparatus and Method," the complete disclosure of which is incorporated by reference herein.

A more recent concept for treating heart failure applies one or more splints onto the heart, and particularly the left ventricle, to reduce the myocardial muscular stresses encountered during pumping. Many examples of such approaches are disclosed in the incorporated U.S. Patent No. 5,961,440. One example includes one or more transventricular splints placed across the left ventricle. Each splint may

include a tension member extending across the ventricle and anchors disposed on opposite ends of the tension member and placed on the external surface of the heart.

Mitral valve incompetency or mitral valve regurgitation is a common comorbidity of congestive heart failure. As the dilation of the ventricle proceeds, valve function may worsen. The resultant volume overload condition, in turn, increases ventricular wall stress thereby advancing the dilation process, which may further worsen valve dysfunction.

In heart failure, the size of the valve annulus (particularly the mitral valve annulus) increases while the area of the leaflets of the valve remains constant. This may lead to an area of less coaptation of the valve leaflets, and, as a result, eventually to valve leakage. Moreover, in normal hearts, the annular size contracts during systole, aiding in valve coaptation. In heart failure, there is poor ventricular function and elevated wall stress. These effects tend to reduce annular contraction and distort annular size, often exacerbating mitral valve regurgitation. In addition, as the chamber dilates, the papillary muscles (to which the leaflets are connected via the chordae tendoneae) may move radially outward and downward relative to the valve, and relative to their normal positions. During this movement of the papillary muscles, however, the various chordae lengths remain substantially constant, which limits the full closure ability of the leaflets by exerting tension prematurely on the leaflets. This condition is commonly referred to as "chordal tethering." The combination of annular changes and papillary changes results in a poorly functioning valve.

It has been observed that for at least certain placements, or orientations, of the one or more transventricular splints in humans, a pre-existing mitral valve incompetency can be exacerbated by the presence and impact of the tightened splints. The splints and the local deformation they impart may further alter the positions of the papillary muscles in such a way that the chordae do not allow as complete of a closure of the mitral valve, or that rotation of portions of the ventricular wall (to which additional chordae may be attached) may "tighten" one valve leaflet and "loosen" the



other. In this manner, the leaflets may not close at the same level relative to the annulus, causing increased retrograde leakage through the valve.

Even in instances where the placement of splints does not contribute to further mitral valve leakage, it may be desirable to provide a therapy which could also correct the valve incompetency. A heart with even a small amount of regurgitation may benefit from not only the stress reducing functions of the ventricular splints as described above, but also from the elimination of the regurgitation, which will further off-load the pumping requirements of the myocardium.

While currently available methods of mitral valve repair or replacement are possible to employ in conjunction with ventricular splinting, they typically require opening the heart to gain direct access to the valve and its annulus. This type of access necessitates the use of cardiopulmonary bypass, which can introduce additional complications to the surgical procedure. Since the implantation of the splints themselves do not require the patient to be on cardiopulmonary bypass, it would be advantageous to devise a technique which could improve the mitral valve without the need for cardiopulmonary bypass. The ability to improve the mitral valve function without the need for cardiopulmonary bypass would be an advantage, both in conjunction with ventricular splinting, and also as a stand-alone therapy.

#### SUMMARY OF THE INVENTION

Objects and advantages of the invention will be set forth in part in the description which follows, and in part will be obvious from the description, or may be learned by practice of the invention. The objects and advantages of the invention will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims. To achieve the objects and in accordance with the purpose of the invention, as embodied and broadly described herein, one aspect of the invention comprises a method for improving the function of a valve of a heart. The method includes the steps of placing an elongate member transverse a heart chamber so that each end of the elongate member extends through a wall of the heart, and

placing first and second anchoring members external to the chamber. The first and second anchoring members are attached to first and second ends of the elongate member to fix the elongate member in a position across the chamber so as to reposition papillary muscles within the chamber.

According to another aspect, the invention comprises a method for improving the function of a valve of a heart. The method includes the steps of placing an elongate member transverse a heart chamber so that a first end of the elongate member extends through a wall of the heart between two papillary muscles, and a second end of the elongate member extends through a septum of the heart; placing a first anchoring member external the heart; and placing a second anchoring member inside the heart adjacent the septum. The first and second anchoring members are attached to the first and second ends of the elongate member respectively to fix the elongate member in a position across the heart chamber.

According to a further aspect, the invention comprises a method for improving the function of a valve of a heart. The method includes the steps of placing an elongate member transverse a heart chamber so that each end of the elongate member extends through a wall of the heart; and placing first and second anchoring members external the chamber. The first and second anchoring members are attached to the ends of the elongate member to fix the elongate member in a position across the chamber. The position is superior to the papillary muscles and proximate and substantially across the valve.

According to an even further aspect, the invention comprises a splint for improving the function of a valve of a heart. The splint includes an elongate member configured to be positioned transverse a heart chamber so that each end of the elongate member extends through a wall of the heart, and first and second anchoring members configured to be positioned external the chamber and attached to the ends of the elongate member to fix the elongate member in a position across the chamber. The first anchoring member includes a first portion configured to contact a first region

of the heart proximate the valve to change a shape of the valve. Preferably, the first portion will contact a first region of the heart proximate the valve annulus to change the shape of the valve annulus.

According to another aspect, the invention comprises a splint for improving the function of a valve of a heart. The splint includes an elongate member configured to be positioned transverse a heart chamber so that each end of the elongate member extends through a wall of the heart, first and second anchoring members configured to be positioned external the chamber and attached to the ends of the elongate member to fix the elongate member in a position across the chamber, a third anchoring member connected to at least one of the first and second anchoring members by a connection member. The third anchoring member is configured to contact a region of the heart proximate the valve to change a shape of the valve.

According to a further aspect, the invention comprises a device for improving the function of a valve of a heart. The device includes a first splint having a first elongate member configured to be positioned transverse a heart chamber so that each end of the elongate member extends through a wall of the heart, and a first anchoring member configured to be positioned external the chamber and attached to a first end of the first elongate member. The device further includes a second splint having a second elongate member configured to be positioned transverse a heart chamber so that each end of the second elongate member extends through a wall of the heart, and a second anchoring member configured to be positioned external the chamber and attached to a first end of the second elongate member. The device also includes a connecting mechanism configured to be connected to the second ends of each of the first and second elongate members external the chamber and press the wall of the heart chamber to change a shape of the valve.

Yet a further aspect of the invention includes a method for improving cardiac function, comprising placing a first member relative to a heart chamber to alter the

cross-sectional shape of the chamber and placing a second member relative to a valve of the heart chamber to assist in apposition of leaflets of the valve.

According to an even further aspect, the invention includes a method of improving the function of a valve of a heart comprising applying a force to an exterior surface of a wall surrounding a chamber of the heart substantially at a location of the valve to alter a shape of the valve.

Yet a further aspect of the invention includes a method for improving the function of a valve of a heart comprising placing a device relative to the heart to alter a shape of the valve and adjusting the device relative to the heart based on data obtained during the adjusting from real-time monitoring of valve function.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and together with the description, serve to explain the principles of the invention.

Fig. 1 is a transverse cross section of the left and right ventricles of a human heart showing the placement of splints according to an orientation for lessening myocardial muscular stresses;

Fig. 2a is a transverse cross section of the left and right ventricles of a human heart showing the orientation of splints according to an embodiment of the present invention for lessening myocardial muscular stresses and assisting in apposition of valve leaflets;

Fig. 2b is a vertical cross section of the left and right ventricles of a human heart showing another orientation of ventricular shape change splints according to an

embodiment of the present invention for lessening myocardial muscular stresses and assisting in apposition of valve leaflets;

Fig. 3a is a transverse cross section of the left and right ventricles of a human heart showing an orientation of a mitral valve splint used in combination with a series of transventricular splints according to an embodiment of the present invention for lessening myocardial muscular stresses and assisting in apposition of valve leaflets;

Fig. 3b is an external view of a human heart showing the orientation of the mitral valve splint and series of transventricular splints of Fig. 3a;

Fig. 3c is a transverse cross section of the left and right ventricle of a human heart showing a various orientations for a mitral valve splint used in combination with a series of transventricular splints according to an embodiment of the present invention;

Fig. 4a is an external view of a human heart showing a series of transventricular splints, with the superior-most splint having an anchor structure according to an embodiment of the present invention that assists in apposition of valve leaflets;

Fig. 4b is an external view of a human heart showing a series of transventricular splints, with the superior most splint having an anchor structure and a connection mechanism between the superior most and middle anchors according to yet another embodiment of the present invention that assists in apposition of valve leaflets;

Fig. 4c is a perspective view of an anchor assembly for a transventricular splint according to yet another embodiment of the present invention that assists in apposition of valve leaflets and repositioning of papillary muscles;

Fig. 5a is a transverse cross section of the left and right ventricles of a human heart showing the placement of splints according to an orientation for lessening myocardial muscular stresses with an accessory anchor assembly according to an embodiment of the present invention to assist in apposition of valve leaflets;

Fig. 5b is a transverse cross section of the left and right ventricles of a human heart showing the placement of splints according to an orientation for lessening myocardial muscular stresses with an accessory anchor assembly according to another embodiment of the present invention to assist in apposition of valve leaflets;

Fig. 6 is a transverse cross section of the left and right ventricles of a human heart showing an orientation of a mitral valve splint used in combination with a series of transventricular splints, with an interconnecting mechanism according to an embodiment of the present invention for lessening myocardial muscular stresses and assisting in apposition of valve leaflets; and

Fig. 7 is a perspective view of a heart with an external splint device and mitral valve anchor assembly and connecting mechanism disposed relative to the left ventricle to alter the shape of the left ventricle and to assist in apposition of valve leaflets according to an embodiment of the present invention.

#### DESCRIPTION OF THE PREFERRED EMBODIMENTS

The various aspects of the invention to be discussed herein generally pertain to devices and methods for treating heart conditions, including, for example, dilatation, valve incompetencies, including mitral valve leakage, and other similar heart failure conditions. Each device of the present invention preferably operates passively in that, once placed in the heart, it does not require an active stimulus, either mechanical, electrical, or otherwise, to function. Implanting one or more of the devices of the present invention operates to assist in the apposition of heart valve leaflets to improve valve function. In addition, these devices may either be placed in conjunction with other devices that, or may themselves function to, alter the shape or geometry of the heart, locally and/or globally, and thereby further increase the heart's efficiency. That is, the heart experiences an increased pumping efficiency through an alteration in its shape or geometry and concomitant reduction in stress on the heart walls, and through an improvement in valve function.

The inventive devices and related methods offer numerous advantages over the existing treatments for various heart conditions, including valve incompetencies. The devices are relatively easy to manufacture and use, and the surgical techniques and tools for implanting the devices of the present invention do not require the invasive procedures of current surgical techniques. For instance, the surgical technique does not require removing portions of the heart tissue, nor does it necessarily require opening the heart chamber or stopping the heart during operation. For these reasons, the surgical techniques for implanting the devices of the present invention also are less risky to the patient than other techniques. The less invasive nature of the surgical techniques and tools of the present invention may also allow for earlier intervention in patients with heart failure and/or valve incompetencies.

The disclosed inventive devices and related methods involve geometric reshaping of the heart and treating valve incompetencies. In certain aspects of the inventive devices and related methods, substantially the entire chamber geometry is altered to return the heart to a more normal state of stress. Models of this geometric reshaping, which includes a reduction in radius of curvature of the chamber walls, can be found in U.S. Patent No. 5,961,440 incorporated above. Prior to reshaping the chamber geometry, the heart walls experience high stress due to a combination of both the relatively large increased diameter of the chamber and the thinning of the chamber wall. Filling pressures and systolic pressures are typically high as well, further increasing wall stress. Geometric reshaping according to the present invention reduces the stress in the walls of the heart chamber to increase the heart's pumping efficiency, as well as to stop further dilatation of the heart.

Although many of the methods and devices are discussed below in connection with their use in the left ventricle and for the mitral valve of the heart, these methods and devices may be used in other chambers and for other valves of the heart for similar purposes. One of ordinary skill in the art would understand that the use of the devices and methods described herein also could be employed in other chambers and

for other valves of the heart. The left ventricle and the mitral valve have been selected for illustrative purposes because a large number of the disorders that the present invention treats occur in the left ventricle and in connection with the mitral valve. Furthermore, the devices disclosed herein for improving valve function can be "stand-alone" devices, that is, they do not necessarily have to be used in conjunction with devices for changing the shape of a heart chamber or otherwise reducing heart wall stress. It also is contemplated that a device for improving valve function may be placed relative to the heart without altering the shape of the chamber, and only altering the shape of the valve itself.

Reference will now be made in detail to the present preferred embodiments of the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

A currently preferred orientation of transventricular splints for lessening myocardial muscular stresses is shown in Figure 1, which shows the short-axis left ventricular cross-section from an anterior perspective. Examples of particular transventricular splints that are especially suitable for this application include those shown and described in copending U.S. Patent Application Serial No. 09/532,049 to Vidlund et al., filed March 21, 2000, entitled "A Splint Assembly for Improving Cardiac Function in Hearts, and Method for Implanting the Splint Assembly," and commonly assigned to the assignee of the present invention. The complete disclosure of that application is incorporated by reference herein. That application will be referred to as "the '049 application" in the remainder of this disclosure.

In the preferred orientation shown in Figure 1, three splints are placed in a coplanar fashion, along the long axis of the ventricle, bisecting the left ventricle LV of the heart 10. Figure 1 is a cross-section (short axis) view looking from the superior side of the heart. The superior-most splint 14 is placed at approximately the level of the heads of the papillary muscles PM and below the level of leaflet coaptation, and



the additional two splints (not shown in Figure 1) are placed inferiorly toward the apex. The preferred orientation shown in Figure 1 both bisects the left ventricle LV and avoids key structures such as coronary vessels and the like. The splints according to this orientation also extend through the septum S near its edge and enter a small portion of the right ventricle RV.

Each splint includes a tension member 16 and an anchor assembly 18 at each end of the tension member 16. Presently preferred embodiments of tension members 16, anchor assemblies 18, and their connection to one another are disclosed in the '049 application incorporated by reference above. As shown in Figure 1, tension member 16 extends through the heart wall HW, across the left ventricle LV, and through the septum S and a portion of the right ventricle RV. Anchor assemblies 18 are placed adjacent the external surface of the heart wall HW.

As mentioned above, human implantations of splints, including in an orientation shown in Figure 1, may exacerbate any pre-existing mitral valve incompetency, including mitral valve regurgitation (MVR), or at the least, may not improve any pre-existing MVR. Figure 2a shows an orientation of splints 14 according to an embodiment of the present invention which may assist in both offloading myocardial wall stress and in aiding the apposition of valve leaflets. According to this orientation, each tension member 16 of splint 14 extends through the heart wall HW at a position approximately midway between the antero lateral papillary muscle PM and the postero medial papillary muscle PM, extends transverse the left ventricle LV, and extends through the septum S at approximately its midpoint. A first anchor assembly 18 is placed external the heart 10 adjacent the heart wall HW and a second anchor assembly is placed inside the right ventricle RV adjacent septum S. Figure 2a shows the superior-most splint 14 of preferably three splints, with the other two splints placed inferiorly towards the apex. More or less than three splints may be used. The splints in this orientation are generally parallel to one another and substantially perpendicular to the long axis of the left ventricle.

The orientation of splints 14 shown in Figure 2a helps to "pull" both of the papillary muscles PM toward the center of the left ventricle LV and reposition those muscles closer to their normal physiological position relative to the mitral valve annulus during the complete cardiac cycle. During the course of heart failure dilation, the papillary muscles PM are moved laterally away from their normal position, which causes the chordae connected to both valve leaflets to become excessively taut. This in turn inhibits the leaflets from fully closing against each other. By bringing the papillary muscles PM closer to the center of the ventricle LV, the chordae are slackened enough to allow the leaflets to appose, thereby improving on mitral valve function. Additionally, although the splints 14 in this approach are preferably positioned at and below the level of the tops of the papillary muscles PM, the shape change deformation at the superior-most splint 14 would extend in a region further superior, and potentially include the annulus itself. To the extent that the annulus in the region of the posterior leaflet is deformed, this would further benefit the valve function by reducing the cross-sectional area of the annulus and positioning the posterior leaflet and its attachment zone closer to the anterior annulus. This, in turn, will cause the leaflets to more fully appose, minimizing MVR.

Various methods may be employed to implant the splints 14 in the orientation shown in Figure 2a. One particularly advantageous method is an endovascular delivery technique shown and described in co-pending U.S. Patent Application Serial No. \_\_/\_\_, to Robert M. Vidlund et al., entitled "Endovascular Splinting Devices and Methods," filed on the same day as this application and commonly assigned to the assignee of this application, the entire disclosure of which is incorporated by reference herein. Splints 14 also may be positioned in the orientation shown in Figure 2a by other surgical techniques, such as those described in the '049 application incorporated by reference above. For example, to gain access to the ventricular septum S, a small incision can be placed within the right ventricular wall to allow for positioning tension member 16 and the anchor assembly 18 within the right ventricle RV. The methods

of implantation shown and described in the applications referred to above may be used in connection with any of the embodiments shown and described herein.

Figure 2b shows another orientation of splints 14 according to an embodiment of the present invention which may assist in the offloading of myocardial wall stress and in the apposition of valve leaflets. According to this orientation, at least one splint 14 is angled with respect to the long axis of the left ventricle LV, in contrast to orienting the at least one splint 14 perpendicular to the axis of the left ventricle LV. In the embodiment shown in Figure 2b, the lower two splints 14 are angled relative to the ventricular axis and relative to the superior-most splint 14, which is approximately perpendicular to the ventricular axis. In this example, all three splints 14 are coplanar, as is preferred for optimizing the ventricular shape change. While Fig. 2b illustrates the ventricular splints having an anchor pad disposed on the septum, it is contemplated that the benefits of angling one or more splints relative to the long axis of the ventricle could be achieved at other cross-sectional orientations including, for example, the orientation shown in Fig. 1, in which an anchor pad is located on an exterior wall of the heart as opposed to the septum wall.

Because the lower two splints 14 are positioned at an angle, they tend to "lift" one or both papillary muscles PM as they impart shape change to the left ventricle LV. By lifting the papillary muscle(s) PM, some slack may be provided to the chordae connected to the valve leaflets to permit improved apposition of the leaflets of mitral valve MV. It is contemplated that more or less splints than the lower two splints may be angled (other than perpendicularly) relative to the ventricular axis to achieve the benefits to MVR, and that each splint may have a different angle relative to that axis. For example, all three splints could be angled, or only one splint could be angled. The number of splints to be angled, and the degree of such angles, would be chosen to optimize the improvement in MVR and would depend on factors such as the particular anatomy of a heart. The splint positioning can be iteratively changed and the impact on MVR, and mitral valve function in general, can be monitored using appropriate

"real-time" imaging techniques and equipment, such as, for example, ultrasound and other suitable mechanisms. The ventricular splints 14 shown in Figure 2b may be oriented in any suitable cross sectional position, including the positions shown in Figures 1 or 2a. The benefits to MVR of angularly positioning one or more of the ventricular splints 14 relative to the ventricular axis, as shown in Figure 2b, may be achieved independent of the particular cross sectional position of the splints 14.

According to an embodiment of the present invention, a method of improving mitral valve function, while maintaining the positions and orientations of the ventricular splints shown in Figure 1, includes the use of an additional splint. This additional splint, referred to herein as a mitral valve splint or MV splint, preferably has the same construction as the other splints and may be implanted using the similar delivery techniques. The primary function of the MV splint is to impart a shape change to the mitral valve annulus, adjacent the left ventricular wall, as well as reposition the papillary muscles PM.

Figures 3a and 3b show an MV splint according to an embodiment of the present invention. Figures 3a and 3b show the three ventricular splints 14 in the positions and orientations shown and described in connection with Figure 1 (the dashed lines in Figures 3a, 3b) and show an exemplary orientation of an MV splint 20. It should be noted that in Figures 3a and 3b the shape change to the left ventricle caused by the transventricular splints 14 is not illustrated. MV splint 20 is positioned superior to the papillary muscles PM and oriented primarily across the mitral valve MV and on or below the mitral valve annulus while avoiding key vascular structures. In this orientation, MV splint 20 is "out of plane" with the other ventricular splints 14, as the overall function of MV splint 20 is to improve and optimize the mitral valve function. In the example shown in Figures 3a and 3b, the MV splint extends through the heart wall between the papillary muscles of the left ventricle LV, and extends transverse the left ventricle LV, through the septum S, through the right ventricle RV, and once again through the heart wall.

The MV splint 20 improves mitral valve function through a combination of effects. First, the shape of the annulus is directly altered, preferably during the entire cardiac cycle, thereby reducing the annular cross sectional area and bringing the posterior leaflet in closer apposition to the anterior leaflet. Second, the position and rotational configuration of the papillary muscles PM and surrounding areas of the left ventricle LV are further altered by the tightening of the MV splint 20. This places the chordae in a more favorable state of tension, allowing the leaflets to more fully appose each other. Third, since the annulus of the valve is muscular and actively contracts during systole, changing the shape of the annulus will also reduce the radius of curvature of at least portions of the annulus, just as the shape change induced by the ventricular splints reduces the radius of at least significant portions of the ventricle. This shape change and radius reduction of the annulus causes off-loading of some of the wall stress on the annulus. This, in turn, assists the annulus's ability to contract to a smaller size, thereby facilitating full closure of the mitral valve MV during systole.

The position of the MV splint 20 shown in Figures 3a and 3b is exemplary. The ventricular splints 14 preferably are positioned prior to positioning MV splint 20, through the use of, for example, both angiographic and ultrasonic visualization tools. This positioning technique, described in the '049 application incorporated above, achieves optimal positioning of splints 14 to bisect the left ventricle LV and avoid key anatomic structures. After positioning the ventricular splints 14, a device such as the probe/marketing device shown and described in the '049 application may be used to repeatedly probe and deform possible areas near the mitral valve to find the optimal position for the MV splint 20. By utilizing, for example, standard "real-time" ultrasonic imaging techniques, the direct impact of the probing on MVR can be assessed, and pre-existing MVR or MVR exacerbated by placement of the ventricular splints 14 can be corrected. Once the optimal position for an MV splint 20 is determined and marked, the MV splint 20 is implanted and positioned by any of the delivery techniques referred to above, including the endovascular delivery technique

or the more direct surgical approaches. The use of the MV splint 20 allows for the optimal placement of the ventricular splints 14, which reduce heart wall stress, independent from the optimal subsequent positioning of the MV splint 20, which improves mitral valve function. During implantation, the splint can be adjusted (either in position or in tightness or both) to optimize improvement to valve function, as determined by observation of the valve using real-time imaging techniques.

It is anticipated that the optimal position of the MV splint 20 could be at virtually any orientation relative to the valve leaflets, depending on the heart failure and mitral valve regurgitation associated with the particular heart at issue. For example, in some hearts, the position shown and described in connection with Figures 3a and 3b may yield the most improvement of MVR, whereas in other hearts, alternative positions such as shown in Fig. 3c may yield the most improved results. Note that in Figure 3c, the transventricular splint is shown positioned between the papillary muscles, which may be another preferred orientation for certain hearts. Alternative "A" places MV splint to cause shape change between the papillary muscles. Alternative "B" for MV splint positioning would be in a line more parallel to the valve leaflet edges, as shown in Figure 3d. Other placements of the MV splint, as well as the position of the transventricular splints, relative to the heart also are contemplated and could be selected based on the condition of the heart and the mitral valve.

According to another embodiment of the present invention, an alternative anchor assembly for the ventricular splints 14 may be provided to aid in mitral valve function. In the embodiment shown in Figure 4a, the superior-most splint 14 includes an anchor assembly 28 configured for connection to the "free wall" end of that splint 14, i.e., at the exterior wall of the left ventricle. Anchor assembly 28 includes a lower portion in the form of, for example, a lower pad portion 30 which contacts the external surface of the left ventricle wall somewhat below the level of the tension member 16. In a preferred embodiment, the lower pad portion 30 resembles the

shape, size, and construction of the anchor pads described in the '049 application incorporated above. Anchor assembly 28 further includes an upper portion in the form of, for example, an upper pad portion 34 which contacts a superior region of the left ventricle wall near the mitral valve annulus. Tension member 16 connects to a spanning structure 32 that, in one embodiment, is preferably integrally fabricated with the lower and upper pad portions 30 and 34, and connects portions 30 and 34. Suitable materials for anchor assembly may include, but are not limited to, those described in the '049 application. At least the lower and upper pad portions 30 and 34 preferably include a covering or a coating of a material, such as, for example, a woven polyester fabric, to encourage tissue in-growth. The spanning structure 32 also may be made of, or include a covering or coating made of, a material to encourage tissue in-growth

In the exemplary, preferred embodiment shown in Figure 4a, the lower pad portion 30 has a circular shape and the upper pad portion 34 has an oblong shape. The oblong shape of the upper pad portion 34 has the advantage of inducing relatively extensive shape change along the periphery of the valve annulus, preferably during the entire cardiac cycle. Therefore, in an embodiment, the length and shape of the upper pad portion may extend a significant distance around the valve annulus. For example, the upper pad portion 34 may extend from about 1 cm in length to about 10 cm in length, depending on the desired shape change of the valve annulus. The width of the upper pad portion 34, however, is preferably relatively narrow, so as to concentrate its shape change impact to the region near the valve annulus.

The upper pad portion 34 may be positioned near, but below, the valve annulus. In other embodiments of the present invention, the upper pad portion may be positioned directly on the exterior surface of the annulus or somewhat above the annulus to contact the left atrium wall. The position of the upper pad portion preferably avoids direct compressive contact with important vascular structure near or on the exterior surface of the heart. Significant coronary vasculature often lies on or

near the atrio-ventricular groove 36, which corresponds with the posterior annular region of the mitral valve. For this reason, it may be desirable to position the upper pad portion onto the left atrial surface.

Anchor assembly 28 permits selection of a position that causes valve annulus shape change relatively independent from the positioning of the ventricular splints that cause ventricular shape change. The incorporation of an anchor assembly 28 is most suitable for instances where the desired shape change for the mitral valve is relatively co-planar with the main ventricular shape change splints. In addition, anchor assembly 28 provides for annulus shape change without the need for an additional MV splint, such as that shown in Figures 3a and 3b.

An alternative embodiment of a splint with a mitral valve anchor assembly according to the invention is illustrated in Figure 4b. In the embodiment of anchor assembly 28, shown in Figure 4a, the tension member 16 was connected to the spanning structure 32 approximately in the middle of the spanning structure 3, yielding a relatively stable structure that remains substantially parallel to the exterior surface of the heart. However, the embodiment of the anchor assembly 28' shown in Figure 4b places the ventricular shape change caused by the lower pad portion 30' below the end of the tension member 16'. The anchor assembly 28' illustrated in Figure 4b is similar to the anchor assembly 28 of Figure 4a, except that the tension member 16' is anchored within the lower pad portion 30'. In order to provide mechanical balance to the anchor assembly, and to give leverage to the upper pad portion 34' such that it can properly alter the region of the valve annulus, a second spanning structure 33 is provided to mechanically connect the anchor assembly 28' to an anchor pad 14 of the splint disposed below the superior-most splint. This second spanning structure 33 also may be integrally formed with the anchor assembly 28' and, in turn, with the anchor pad 14. Alternatively, the second spanning structure 33 can be a separate component connecting anchor assembly 28' and anchor pad 14' once



they are positioned with respect to the heart. This could be done, for example, by mechanical fastening, such as with screws or the like.

A further alternative anchor assembly 28" is shown in Figure 4c. This anchor assembly 28" is similar to the anchor assembly 28 shown in Figure 4a, except that anchor assembly 28" also includes one or more additional papillary pad portions 35 connected to lower pad portion 30" at a location substantially opposite to spanning structure 32". The papillary pad portion or portions 35 serve to provide one or more additional sites of deformation of the ventricular wall, preferably to further reposition one or both papillary muscles to aid in apposition of the valve leaflets. The papillary pad portions 35 may be formed integrally with the anchor assembly 28" or may be separate and connected thereto via suitable connection mechanisms.

In certain cases, the optimal orientation of shape change for improving the mitral valve function may be significantly offset from the position and orientation of transventricular splints 14. It is therefore desirable to have an approach to cause mitral valve shape change at positions away from the transventricular splints 14, and even more desirably, without the addition of another splint structure traversing the ventricle.

Figure 5a shows such an approach according to an embodiment of the present invention. Figure 5a shows an accessory anchor pad structure 40 attached to a connection member, shown as a runner 42. Runner 42 connects at its ends to both anchor pads 18 of preferably the superior-most splint assembly 14. As an alternative, runner 42 may connect to one anchor pad 18 and extend between that anchor pad 18 and structure 40. The accessory pad structure 40 is positioned at the location on the heart wall that yields the greatest improvement in MVR, as determined with repeated probing and deforming at the exterior of the heart proximate the mitral valve annulus, as described above in connection with positioning the MV splint 20 in Figures 3a and 3b.

Since runner 42 preferably connects to the two anchor pads 18 of the upper-most splint assembly 14, runner 42 generally runs at approximately the same level on the heart wall as those anchor pads 18. In one embodiment, accessory anchor pad structure 40 may be of the same shape and material as the anchor pads 18. While this embodiment may result in significantly improved MVR in some instances, in another embodiment, accessory pad 40 may take a form, including shape and material, similar to the anchor assemblies 28, 28', 28'' shown in Figures 4a-4c. This latter configuration permits positioning accessory pad 40 at a position higher than the level of the anchor pads 18 of the superior-most transventricular splint, resulting in even greater shape change to the mitral valve annulus. Also according to this latter configuration, the preferred construction of accessory pad 40 would include, in addition to characteristics of anchor assembly 28, 28', 28'', shown in Figures 4a-4c, a connecting mechanism 41 which would allow for adjustable positioning and securing of the accessory pad 41 to runner 42. For example, a locking screw 43 may be used to secure runner 42 to pad 41. Other mechanisms suitable for securing the pad 41 to the runner 42 and permitting adjustment of the pad position along the runner are within the scope of the present invention. Runner 42 preferably includes a wire-like, or braid-like, structure which secures to each of the splint anchor pads 18 also through any suitable means, such as, for example, a locking screw mechanism 44, a pinning connection for a braid-like runner, or the like.

Figure 5b shows an alternative embodiment for connecting an accessory anchor pad assembly 50 to a runner 52 and for connecting runner 52 to anchor pads 18. Each end of runner 52 connects to a connection mechanism in the form of a cap 54. Each cap 54 locks in place over a pad 18. At least one of the caps 54 includes an adjustable locking mechanism for adjusting the length of the runner 52 between the caps 54, and also thereby adjusting the position of the accessory pad 50 on the heart wall, and locking the runner 52 to cap 54.

In one embodiment, runner 52 is a braid formed of a high strength polymer, such as that used in the tension members described in the '049 application incorporated above. A suitable connection mechanism includes the use of one or more pins 56 placed through the braided runner 52 and connected to cap 54 through a flange 58, for example, situated on the cap 54. This pinning connection mechanism may be similar to the connection used for the braided tension members and anchor pads shown and described in the '049 application. The same connection mechanism may be used to connect accessory pad 50 to braided runner 52. In an alternative embodiment according to the present invention, the braided runner 52 may more directly connect to anchor pads 18, without the use of caps 54, by, for example, a pinning securement mechanism incorporated into the superior splint pads themselves. In another contemplated embodiment, the external anchor pad assembly 50, including the runner 52 and anchor pads 18, can be used without the transventricular splint to improve valve function by causing a shape change to the valve annulus without an overall shape change to the left ventricle.

As mentioned above, a mechanism that may exacerbate MVR is the relative rotation of the papillary muscles PM and the adjacent left ventricular wall as the transventricular splints 14 are tightened into position. This relative rotation results in slack in some chordae and tightening in other chordae, which may "pull" one valve leaflet (or portion of the leaflet) while "loosening" the other valve leaflet (or portion of the leaflet).

Figure 6 shows an embodiment of a device according to the present invention that would alleviate this rotation phenomenon. Figure 6 shows an accessory splint 70 connected to the superior-most ventricular splint 14 by a connecting bar 60. Accessory splint 70 and connecting bar 60 preferably are placed at approximately the same level along the ventricular wall as splint 14. Splint 14 preferably is positioned near to, and in this case medial to, the anterior papillary muscle PM. Accessory splint 70 then is positioned through the septum S, across the left ventricle LV, and through

the ventricular free wall between the papillary muscles PM, similar to MV splint 20 described in connection with Figures 3a and 3b but at about the same level as the superior splint 14.

Connecting bar 60 attaches to the ends of tension members 16 and 72 at their left ventricular "free wall" ends. Both tension members 16 and 72 are tensioned, pressing connecting bar 60 into the left ventricle and effecting shape change to the ventricle and the mitral valve annulus. Connecting bar 60 prevents rotation of the left ventricle LV in the region of the anterior papillary muscle PM and causes uniform tensioning of the chordae associated with that papillary muscle PM and any associated ventricular wall. This is believed to lessen any degradation in MVR, and potentially improve the MVR, because the papillary muscles PM are brought to a more desired position, with less rotation, particularly as to the anterior papillary muscle.

The embodiments of the present invention described in connection with Figures 2a to 6 have been described in connection with the use of transventricular splints used to geometrically reshape a chamber of the heart and thereby lessen heart wall stresses and reduce dilatation. While the devices and related methods described herein would further benefit the ventricular splinting procedure and its effects, the devices and related methods of the present invention may be used independent of the ventricular splinting to improve dilatation and instead be used for repairing heart valves, and particularly mitral valves, without the use of adjunctive ventricular splints. For example, a mitral valve splint such as that shown in Figs. 3a, 3b, and 3c could be utilized without additional ventricular shape change splints.

Moreover, while many of the embodiments of the present invention have been described in connection with modifications to transventricular splinting structures, the same or similar modifications may be made to external-type devices for causing ventricular shape change. Examples of such external devices are shown in co-pending U.S. Patent Application Serial No. 09/157,486 ("the '486 application") filed September 21, 1998 and entitled "External Stress Reduction Device and Method," the

complete disclosure of which is incorporated by reference herein. Modifying those external devices in a similar manner as with the transventricular splints will achieve beneficial impacts to the mitral valve function. For example, the accessory anchor pad shown in Figs. 5a and 5b could be utilized in conjunction with an external stress reduction device, as shown, for example, in Fig. 7. In Fig. 7, an external splint 199 having a generally U-shaped configuration and including an anterior arm 199a and a posterior arm 199b, is positioned with respect to the left ventricle to create a substantially bi-lobed shape. In a preferred embodiment, the U-shaped external splint is made from a material that permits the splint to elastically deform under operational loads and also from a material that is biocompatible. Examples of preferred materials include e-PTFE, or a polyester such as Dacron, for example. Such a splint, as well as other suitable external splints, is described in more detail in the '486 application incorporated above. As shown in Fig. 7, a runner 298, similar to the runner described with reference to Figs 5a and 5b, attaches at its ends to the arms 199a, 199b. An accessory anchor pad 299, also similar to the accessory anchor assembly discussed with reference to Figs. 5a and 5b, attaches to the connecting runner 298. The runner 298 and accessory anchor pad 299 are positioned with respect to the heart so as to alter the shape of the mitral valve annulus to assist in coaptation of the valve leaflets. Alternatively, the runner and accessory anchor pad could be positioned so as to provide a repositioning of the papillary muscles, also to assist in coaptation of the valve leaflets.

It will be apparent to those skilled in the art that various modifications and variations can be made in the devices and related methods for improving mitral valve function of the present invention and in construction of such devices without departing from the scope or spirit of the invention. As an example, a combination of devices depicted above may be used for achieving improved mitral valve function. In one such combination, an accessory splint such as MV splint 20 shown in Figures 3a and 3b may include an anchor assembly 28 as shown in Figure 4 and/or an accessory

anchor pad structure 40 or 50 shown in Figures 5a and 5b. Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. The specification and examples are exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

WHAT IS CLAIMED IS:

1. A method for improving the function of a valve of a heart, the method comprising the steps of:

placing an elongate member transverse a heart chamber so that a first end of the elongate member extends through a wall of the heart between two papillary muscles, and a second end of the elongate member extends through a septum of the heart;

placing a first anchoring member external the heart; and

placing a second anchoring member inside the heart adjacent the septum, the first and second anchoring members being attached to the first and second ends of the elongate member respectively to fix the elongate member in a position across the heart chamber.

2. The method of claim 1, wherein the heart chamber is the left ventricle and the valve is the mitral valve.

3. The method of claim 2, wherein the first end of the elongate member extends through a wall of the heart approximately midway between the antero lateral papillary muscle and the posterio medial papillary muscle.

4. The method of claim 3, wherein the elongate member is placed proximate the mitral valve.

5. The method of claim 1, wherein the elongate member is fixed in the position so as to change a shape of the heart chamber.

6. The method of claim 1, wherein the elongate member is fixed in the position so as to reposition the papillary muscles.

7. A method for improving the function of a valve of a heart, the method comprising the steps of:

placing a first elongate member transverse a heart chamber so that each end of the first elongate member extends through a wall of the heart;

placing first and second anchoring members external the chamber, the first and second anchoring members being attached to the ends of the first elongate member to fix the first elongate member in a first position across the chamber;

placing a second elongate member transverse the heart chamber so that each end of the second elongate member extends through a wall of the heart;

placing third and fourth anchoring members external the chamber, the third and fourth anchoring members being attached to the ends of the second elongate member to fix the second elongate member in a second position across the chamber, wherein the first and second positions are substantially coplanar and have differing angles relative to an axis of the chamber.

8. The method of claim 7, wherein the heart chamber is the left ventricle and the valve is the mitral valve.

9. The method of claim 7, wherein the first and second elongate members are fixed in the first and second positions so as to change a shape of the heart chamber.

10. The method of claim 7, wherein the first and second elongate members are fixed in the first and second positions so as to reposition papillary muscles within the chamber.

11. A method for improving the function of a valve of a heart, the method comprising the steps of:

placing an elongate member transverse a heart chamber so that each end of the elongate member extends through a wall of the heart; and

placing first and second anchoring members external the chamber, the first and second anchoring members being attached to the ends of the elongate member to fix the elongate member in a position across the chamber, wherein the position is superior to the papillary muscles and proximate and substantially across the valve.

12. The method of claim 11, wherein the heart chamber is the left ventricle and the valve is the mitral valve.



13. The method of claim 11, wherein the position of the elongate member alters a shape of an annulus of the valve.

14. The method of claim 11, wherein the position of the elongate member repositions the papillary muscles within the chamber.

15. A splint for improving the function of a valve of a heart, the splint comprising:

an elongate member configured to be positioned transverse a heart chamber so that each end of the elongate member extends through a wall of the heart; and

first and second anchoring members configured to be positioned external the chamber and attached to the ends of the elongate member to fix the elongate member in a position across the chamber, wherein the first anchoring member includes a first portion configured to contact a first region of the heart proximate the valve to change a shape of the valve.

16. The splint of claim 15, wherein the heart chamber is the left ventricle and the valve is the mitral valve.

17. The splint of claim 16, wherein the first region of the heart is a superior portion of the left ventricle proximate an annulus of the mitral valve.

18. The splint of claim 16, wherein the first region of the heart is a portion of the left atrium proximate an annulus of the mitral valve.

19. The splint of claim 15, wherein the first portion has an oblong shape.

20. The splint of claim 15, wherein the first anchoring member further includes a second portion configured to contact a second region of the heart below the first region.

21. The splint of claim 20, wherein the second portion includes a first structure connected to the elongate member and a second structure connected to the first portion by the first structure.

22. A splint for improving the function of a valve of a heart, the splint comprising:

an elongate member configured to be positioned transverse a heart chamber so that each end of the elongate member extends through a wall of the heart;

first and second anchoring members configured to be positioned external the chamber and attached to the ends of the elongate member to fix the elongate member in a position across the chamber; and

a third anchoring member connected to at least one of the first and second anchoring members by a connection member, the third anchoring member configured to contact a region of the heart proximate the valve to change a shape of the valve.

23. The splint of claim 22, wherein the third anchoring member connects to the first and second anchoring members by the connection member.

24. The splint of claim 22, wherein the third anchoring member includes a connection mechanism for connecting the third anchoring member to the connection member.

25. The splint of claim 24, wherein the connection mechanism includes a locking screw.

26. The splint of claim 24, wherein the connection mechanism includes a pin.

27. The splint of claim 22, further comprising a connection mechanism for connecting the connection member to the at least one of the first and second anchoring members.

28. The splint of claim 27, wherein the connection mechanism includes a locking screw.

29. The splint of claim 27, wherein the connection mechanism includes a pin.

30. The splint of claim 27, wherein the connection mechanism includes a cap configured to fit over the at least one of the first and second anchoring members.

31. The splint of claim 23, further comprising an adjustment mechanism for adjusting a length of the connection member between the first and second anchoring members.

32. A device for improving the function of a valve of a heart, the device comprising:

a first splint having a first elongate member configured to be positioned transverse a heart chamber so that each end of the elongate member extends through a wall of the heart, and a first anchoring member configured to be positioned external the chamber and attached to a first end of the first elongate member;

a second splint having a second elongate member configured to be positioned transverse a heart chamber so that each end of the second elongate member extends through a wall of the heart, and a second anchoring member configured to be positioned external the chamber and attached to a first end of the second elongate member; and

a connecting mechanism configured to be connected to the second ends of each of the first and second elongate members external the chamber and press the wall of the heart chamber to change the shape of an annulus of the valve.

33. The device of claim 32, wherein the connection mechanism is a bar.

34. The device of claim 32, wherein the heart chamber is the left ventricle and the valve is the mitral valve.

35. The device of claim 32, wherein the device is configured so that the connecting bar presses the wall of the heart chamber to change the shape of chamber.

36. A method for improving the function of a valve of a heart, the method comprising the steps of:

placing an elongate member transverse a heart chamber so that each end of the elongate member extends through a wall of the heart; and

placing first and second anchoring members external the chamber, the first and second anchoring members being attached to first and second ends of the elongate

member to fix the elongate member in a position across the chamber so as to reposition papillary muscles within the chamber.

37. The method of claim 36, wherein the first end of the elongate member extends through a wall of the left ventricle between papillary muscles.

38. The method of claim 37, wherein the second end of the elongate member extends through a septum of the heart.

39. The method of claim 36, wherein the chamber is the left ventricle and the valve is the mitral valve.

40. The method of claim 36, wherein the position is superior to the papillary muscles and proximate and substantially across the valve.

41. The method of claim 36, wherein the elongate member is fixed in the position so as to alter the shape of an annulus of the valve.

42. A method for improving cardiac function, comprising:  
placing a first member relative to a heart chamber to alter the cross-sectional shape of the chamber; and

placing a second member relative to a valve of the heart chamber to assist in apposition of leaflets of the valve.

43. The method of claim 42, wherein each of the first and second members includes a portion placed transverse the chamber.

44. The method of claim 42, wherein each of the first and second members includes an elongate member.

45. The method of claim 44, wherein the placing each of the first and second elongate members includes securing the elongate members relative to the heart chamber with anchors configured to engage each end of the elongate members and configured to engage an exterior surface of a wall surrounding the heart chamber.

46. The method of claim 45, wherein the securing the second elongate member includes engaging one of the anchors with an exterior surface of the heart wall proximate the valve to alter a shape of an annulus of the valve.

47. The method of claim 42, wherein the heart chamber is a left ventricle.

48. The method of claim 42, wherein the valve is a mitral valve.

49. The method of claim 42, wherein the placing the second member includes altering the cross-sectional shape of an annulus of the valve.

50. The method of claim 42, wherein the placing the second member includes reducing a radius of an annulus of the valve.

51. The method of claim 42, wherein the placing the second member includes placing the second member so as to alter a position of at least one papillary muscle of the heart chamber.

52. The method of claim 51, wherein the placing the second member includes securing the second member with respect to the heart chamber with an anchor configured to engage an exterior surface of a wall surrounding the heart chamber substantially at a location of the at least one papillary muscle.

53. The method of claim 42, wherein the placing the first member includes placing an elongate member transverse the heart chamber and through a wall surrounding the heart chamber at substantially opposite locations on the heart wall.

54. A method of improving the function of a valve of a heart, the method comprising:

applying a force to an exterior surface of a wall surrounding a chamber of the heart substantially at a location of the valve to alter a shape of the valve.

55. The method of claim 54, wherein applying the force alters the shape of an annulus of the valve.

56. The method of claim 54, wherein altering the shape of the valve includes appositioning leaflets of the valve.

57. The method of claim 54, wherein altering the shape of the valve includes reducing a radius of an annulus of the valve.

58. The method of claim 54, wherein the force is applied by a device having an elongate member placed transverse the chamber and a first anchor assembly

connected at a first end of the member external the chamber and a second anchor assembly connected at a second end of the member external the chamber.

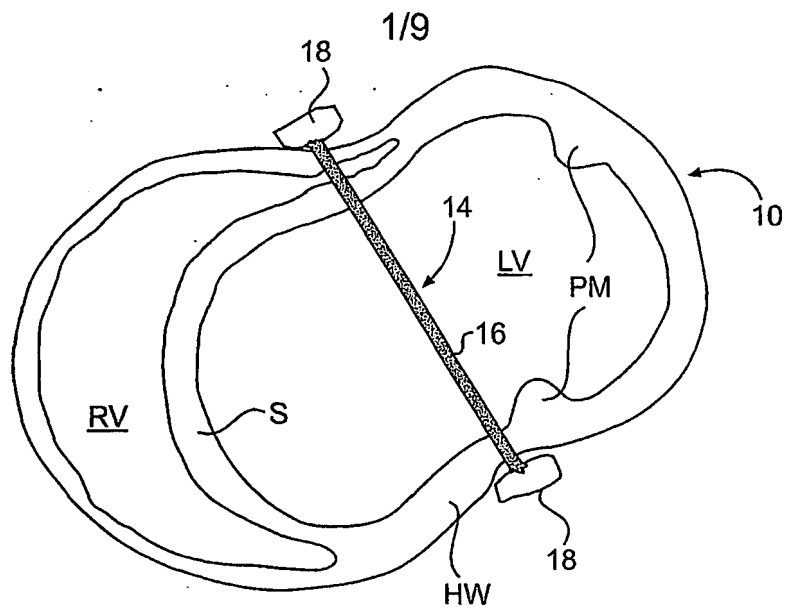
59. A method for improving the function of a valve of a heart, comprising:  
placing a device relative to the heart to alter a shape of the valve; and  
adjusting the device relative to the heart based on data obtained during the  
adjusting from real-time monitoring of valve function.

60. The method of claim 59, wherein the device is a splint.

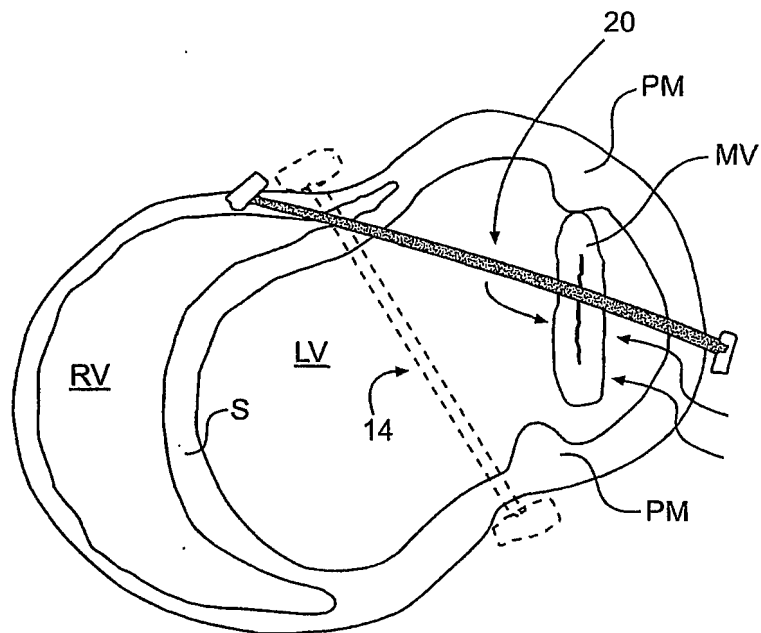
61. The method of claim 59, wherein the device is a splint and adjusting the splint includes changing a distance between at least two portions of the splint that contact respective portions of the heart.

62. The method of claim 59, wherein the real-time monitoring includes imaging the valve.

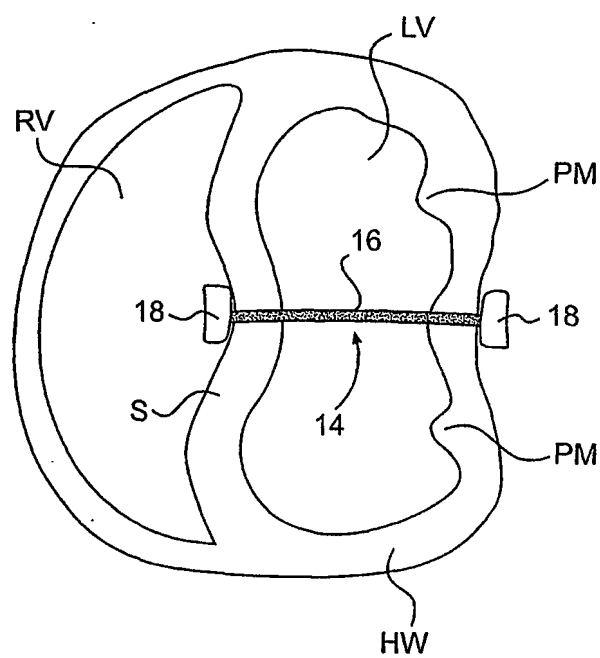
63. The method of claim 62, wherein the imaging of the valve includes ultrasound imaging.



**FIG. 1**

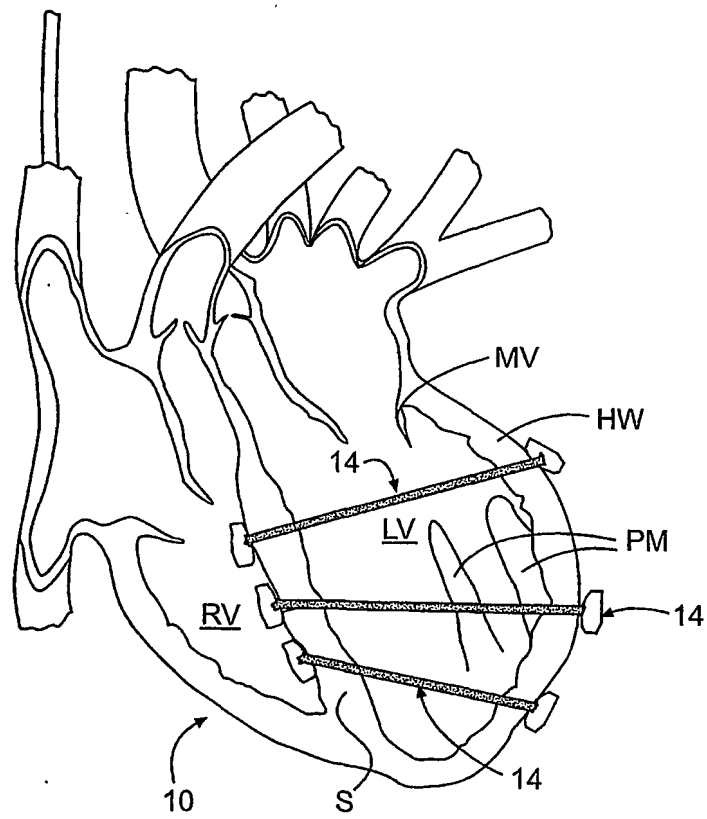


**FIG. 3a**

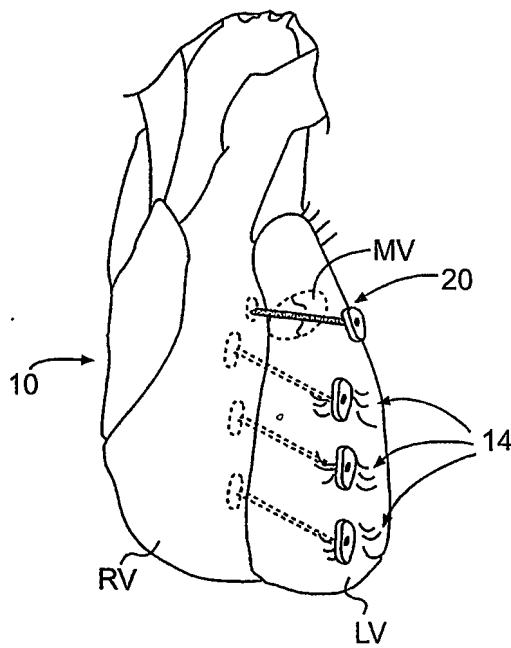


**FIG. 2a**

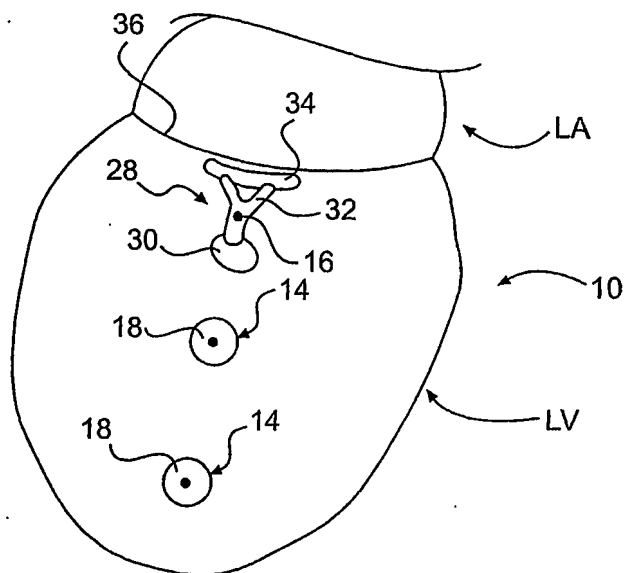




**FIG. 2b**

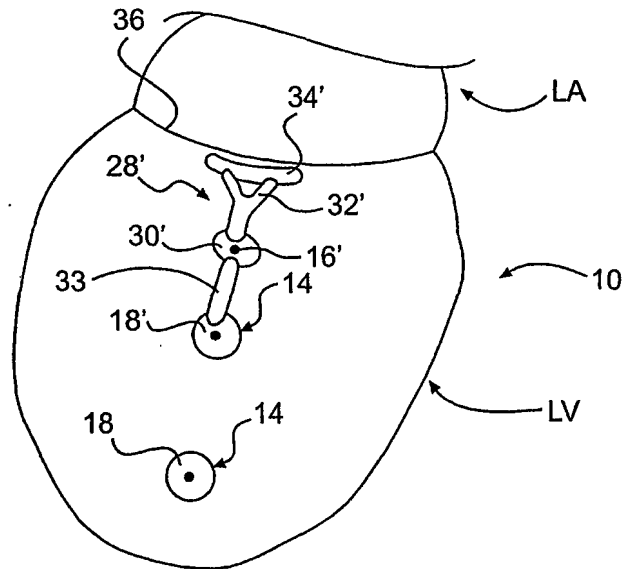


**FIG. 3b**

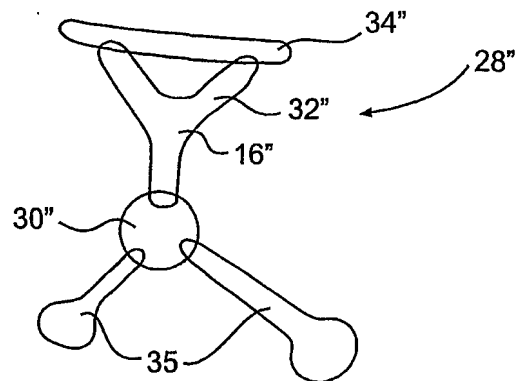


**FIG. 4a**

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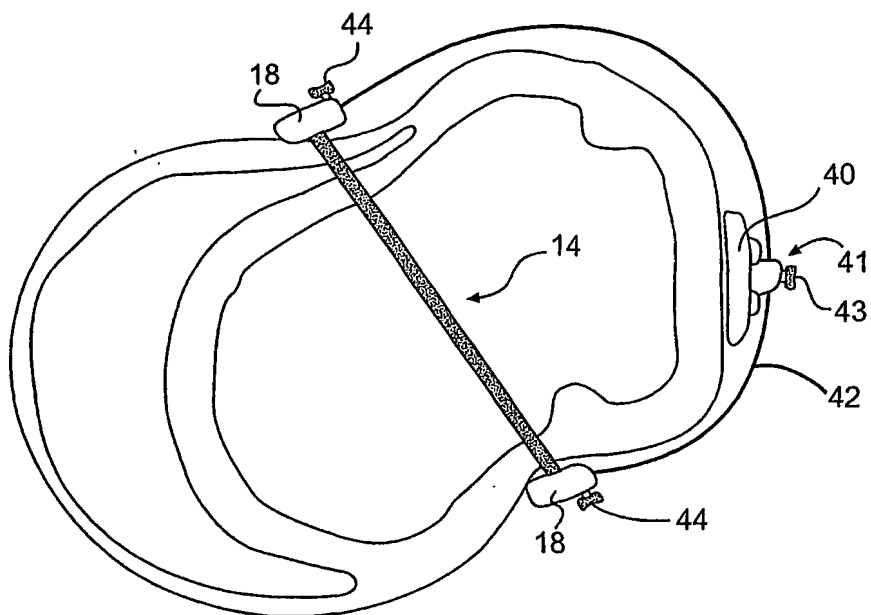


**FIG. 4b**

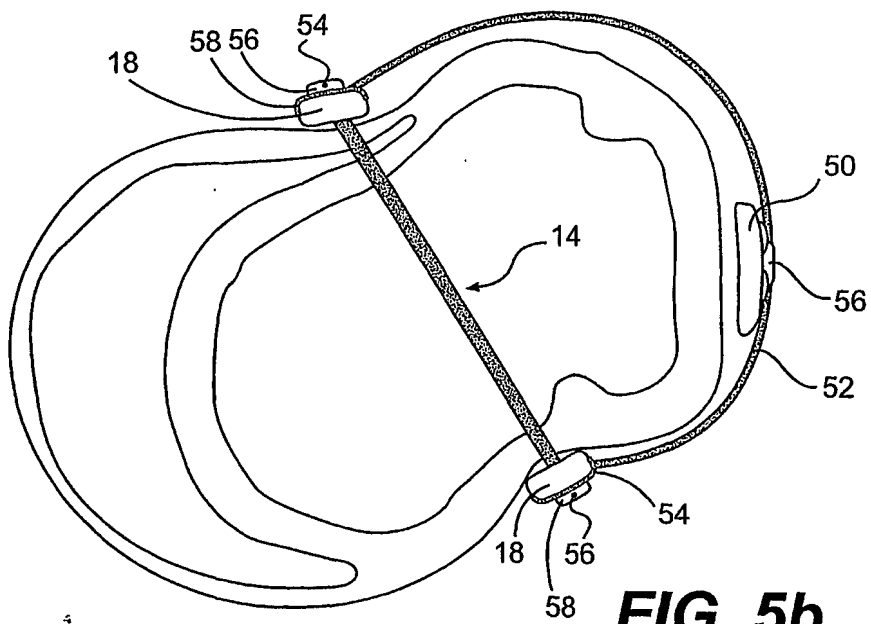


**FIG. 4c**

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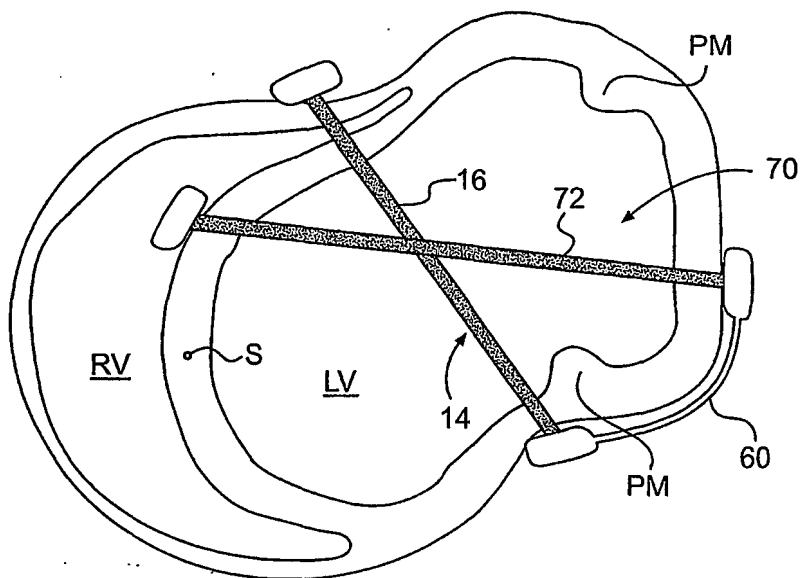


**FIG. 5a**

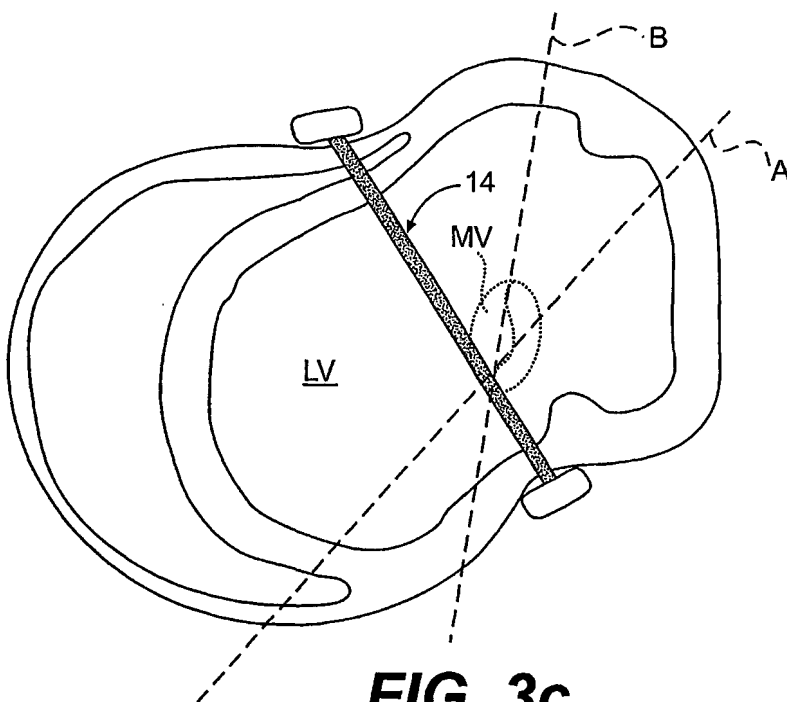


**FIG. 5b**

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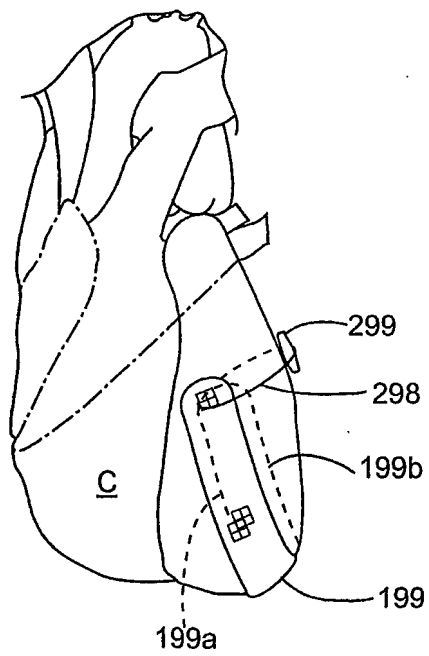


**FIG. 6**



**FIG. 3c**

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**FIG. 7**

## INTERNATIONAL SEARCH REPORT

 Application No  
 PCT/US 01/30882

**A. CLASSIFICATION OF SUBJECT MATTER**  
 IPC 7 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**
 Minimum documentation searched (classification system followed by classification symbols)  
 IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 125 852 A (ROSENMAN DANIEL C ET AL) 3 October 2000 (2000-10-03) column 10, line 28 - column 11, line 3; figures 7A-7C	15, 16
A		22, 32, 34, 35
A	US 6 077 214 A (SCHWEICH JR CYRIL J ET AL) 20 June 2000 (2000-06-20)  column 5, line 55 - line 63; figures 1, 2 figures 11, 12 column 12, line 57 - line 67; figure 35  -/--	15, 16, 22, 32, 34, 35

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

15 February 2002

Date of mailing of the international search report

25/02/2002

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## INTERNATIONAL SEARCH REPORT

In Application No  
PCT/US 01/30882

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00 06028 A (SCHWEICH CYRIL J JR ;KEITH PETER T (US); KUSZ DAVID A (US); MORTIE) 10 February 2000 (2000-02-10) page 51, line 14 -page 53, line 12; figures 72-76	15,16, 22,32, 34,35
A	WO 00 06026 A (SCHWEICH CYRIL J JR ;KEITH PETER T (US); MORTIER TODD J (US); MYOC) 10 February 2000 (2000-02-10) page 13, line 11 - line 22; figures 15,16	15,16, 22,32, 34,35
A	US 5 961 440 A (SCHWEICH JR CYRIL J ET AL) 5 October 1999 (1999-10-05) the whole document	15,22,32

## INTERNATIONAL SEARCH REPORT

In Application No  
PCT/US 01/30882

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6125852	A	03-10-2000	US 5571215 A	05-11-1996
			US 5452733 A	26-09-1995
			AU 3737397 A	10-02-1998
			WO 9803213 A1	29-01-1998
			AU 5951996 A	30-12-1996
			CA 2239907 A1	19-12-1996
			EP 0836423 A1	22-04-1998
			WO 9639942 A1	19-12-1996
			US 6309382 B1	30-10-2001
			US 5849005 A	15-12-1998
			US 6010531 A	04-01-2000
			US 5972030 A	26-10-1999
			US 5713951 A	03-02-1998
			US 5728151 A	17-03-1998
			US 5718725 A	17-02-1998
			US 5682906 A	04-11-1997
			US 5766151 A	16-06-1998
			US 5814097 A	29-09-1998
			US 6029671 A	29-02-2000
			US 5814016 A	29-09-1998
			AU 702940 B2	11-03-1999
			AU 1099595 A	27-06-1995
			CA 2177490 A1	15-06-1995
			EP 0732890 A1	25-09-1996
			JP 9509585 T	30-09-1997
			WO 9515715 A1	15-06-1995
			US 6283127 B1	04-09-2001
			US 5613937 A	25-03-1997
			US 5797960 A	25-08-1998
			US 6079414 A	27-06-2000
			US 5855614 A	05-01-1999
			US 5823956 A	20-10-1998
			US 5829447 A	03-11-1998
			US 5980455 A	09-11-1999
			US 6161543 A	19-12-2000
			US 5924424 A	20-07-1999
			AU 688303 B2	12-03-1998
			AU 6024594 A	14-09-1994
			CA 2154354 A1	01-09-1994
			EP 0684781 A1	06-12-1995
			JP 8511694 T	10-12-1996
			WO 9418881 A1	01-09-1994
			US 5425705 A	20-06-1995
			US 5569274 A	29-10-1996
			US 5735290 A	07-04-1998
			US 6311693 B1	06-11-2001
			US 5536251 A	16-07-1996
			US 6325067 B1	04-12-2001
			US 5799661 A	01-09-1998
			US 5961481 A	05-10-1999
US 6077214	A	20-06-2000	AU 5230999 A	21-02-2000
			EP 1143859 A2	17-10-2001
			WO 0006027 A2	10-02-2000
			US 6264602 B1	24-07-2001
			US 2001016675 A1	23-08-2001
WO 0006028	A	10-02-2000	US 6260552 B1	17-07-2001

## INTERNATIONAL SEARCH REPORT

In at Application No  
PCT/US 01/30882

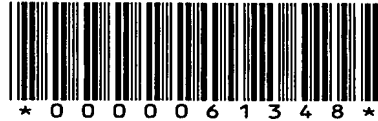
Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0006028 A		AU 5231099 A	21-02-2000
		EP 1100378 A1	23-05-2001
		WO 0006028 A1	10-02-2000
		US 2001025171 A1	27-09-2001
WO 0006026 A	10-02-2000	US 6045497 A	04-04-2000
		AU 5230899 A	21-02-2000
		EP 1143858 A2	17-10-2001
		WO 0006026 A2	10-02-2000
		US 6261222 B1	17-07-2001
US 5961440 A	05-10-1999	US 6050936 A	18-04-2000
		EP 1011461 A1	28-06-2000
		JP 2001508336 T	26-06-2001
		WO 9829041 A1	09-07-1998
		US 6045497 A	04-04-2000
		US 6165119 A	26-12-2000
		US 6261222 B1	17-07-2001
		US 6165120 A	26-12-2000
		US 6332863 B1	25-12-2001
		US 6059715 A	09-05-2000
		US 6162168 A	19-12-2000
		US 6332864 B1	25-12-2001

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